IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W. L. GORE & ASSOCIATES, INC.,	)	
	)	
Plaintiff,	)	C.A. No. _____
	)	
v.	)	
	)	
AGA MEDICAL CORP. and AGA MEDICAL HOLDINGS, INC.,	)	**JURY TRIAL DEMANDED**
	)	
	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff W. L. Gore & Associates, Inc. ("Gore") hereby alleges for its Complaint for Declaratory Judgment against Defendants AGA Medical Corp. and AGA Medical Holdings, Inc. (collectively "AGA"), on personal knowledge as to its own activities and on information and belief as to the activities of others, as follows:

A. NATURE OF THIS ACTION

1. Plaintiff Gore seeks a Declaratory Judgment that the Gore® Septal Occluder medical device does not infringe any valid and enforceable claim of U.S. Patent No. 5,725,552 ("the '552 patent") and U.S. Patent No. 5,944,738 ("the '738 patent") pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, and for such other relief as the Court deems just and proper.

B. THE PARTIES

2. Plaintiff Gore is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 555 Paper Mill Road, Newark, Delaware 19711. Gore was founded in 1958, and its fluoropolymer products provide innovative solutions

EXHIBIT 13

throughout various industries, including medical products, next-generation electronics, and high-performance fabrics such as "GORE-TEX®."

3. On information and belief, Defendant AGA Medical Corp. is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business at 5050 Nathan Lane North, Plymouth, MN 55442. AGA Medical Corp. markets its products through a network of distributors or sales agents throughout the United States, including the state of Delaware and this district.

4. On information and belief, Defendant AGA Medical Holdings, Inc. (collectively with AGA Medical Corp., "AGA"), is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 5050 Nathan Lane North, Plymouth, MN 55442, and is the parent of AGA Medical Corp., which is a wholly owned subsidiary. AGA Medical Holdings, Inc., can be served with process through its registered agent, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

C. JURISDICTION AND VENUE

5. Gore brings this action pursuant to the Federal Declaratory Judgment Statutes 28 U.S.C. §§ 2201-2202, which cause of action arises under the United States Patent Laws, Title 35 of the United States Code.

6. This Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, AGA Medical Corp. is subject to personal jurisdiction in Delaware because of AGA Medical Corp.'s threats of patent infringement directed at Gore, which is located in the State of Delaware, and AGA Medical Corp.'s other activities in Delaware that are distinct from the foregoing threats of infringement including, without limitation, its

frequent contacts within the State of Delaware and its conducting of substantial and regular business in Delaware through the marketing and sales of AGA Medical Corp.'s products in Delaware, including by substantial sales of products it alleges are covered by the '552 patent or the '738 patent.

8. On information and belief, AGA Medical Holdings, Inc. is subject to personal jurisdiction in Delaware because it has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

D. BACKGROUND

10. Since 1975, Plaintiff Gore has sold and continues to sell medical devices containing a unique inventive polymer material—expanded polytetrafluoroethylene (ePTFE) also commonly referred to as "GORE-TEX®." Gore currently has a number of life-saving medical devices that incorporate ePTFE.

11. Among these medical devices, Gore manufactures and sells septal occluders that incorporate innovative solutions and life-saving technology to patients suffering from certain serious heart defects. Septal defects are serious life-threatening conditions in which patients have holes between the chambers of the heart. Septal occluders are medical devices that are implanted within the heart via catheter to close these holes and to treat the septal defects without the need for open heart surgery.

12. Gore currently offers the GORE® HELEX Septal Occluder medical device that utilizes ePTFE. The GORE® HELEX Septal Occluder medical device has been widely

recognized by medical professionals and provides advantages to patients in many circumstances, including for use in the closure of atrial septal defects in infants and children.

13. The novelty of the GORE® HELEX Septal Occluder medical device has been recognized on several occasions by the United States Patent and Trademark Office, which has issued four patents to Gore covering the GORE® HELEX Septal Occluder.

14. Defendant AGA has commercialized a line of AMPLATZER® occluders, which are indicated for the occlusion of atrial septal defects in secundum position or patients who have undergone a fenestrated fontan procedure and who now require closure of the fenestration. Patients indicated for atrial septal defect closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventrical volume overload (*i.e.*, 1.5:1 degree of left-to-right shunt or RV enlargement). On information and belief, those devices were first approved by the FDA on or about December 2001.

E. PATENTS

15. U.S. Patent No. 5,725,552 is entitled "Percutaneous Catheter Directed Intravascular Occlusion Devices," and bears an issue date of March 10, 1998. A copy of the '552 patent is attached hereto as Exhibit 1.

16. U.S. Patent No. 5,944,738 is entitled "Percutaneous Catheter Directed Constricting Occlusion Device," and bears an issue date of August 31, 1999. A copy of the '738 patent is attached hereto as Exhibit 2.

17. Both the '552 patent and the '738 patent are assigned on their face to AGA Medical Corp. On information and belief, Defendant AGA Medical Corp. is the owner of the '552 patent. In the Minnesota Action (defined below), Defendant AGA Medical Corp. claims it is the owner of the '738 patent.

F. EXISTENCE OF AN ACTUAL CONTROVERSY

18. There is an actual controversy within the jurisdiction of this Court under 28 U.S.C. §§ 2201 and 2202.

19. On information and belief, AGA has marked its AMPLATZER® occluders with the ’552 patent and the ’738 patent. Because AGA marks its own products with these patents, Gore believes future infringement litigation with AGA would likely include the ’552 patent and the ’738 patent.

1. MINNESOTA ACTION

20. On August 24, 2010, AGA, by and through its wholly-owned subsidiary AGA Medical Corp., brought a patent infringement action against Gore in the United States District Court for the District of Minnesota (Case No. 0:10-cv-3734 (JNE/JSM)) (“the Minnesota Action”). In the Minnesota Action, AGA accused Gore of infringing and continuing to infringe one of its patents because of Gore’s activities relating to the life-saving GORE® HELEX Septal Occluder. AGA is seeking, *inter alia*, a permanent injunction to prevent patient access to the life-saving GORE® HELEX Septal Occluder. A true and correct copy of that Complaint is attached hereto as Exhibit 3.

21. The only asserted patent in the Minnesota Action is the ’738 patent.

22. On January 18, 2011, AGA served preliminary infringement contentions in the Minnesota Action that accuse the GORE® HELEX Septal Occluder as the only allegedly infringing Gore medical device.

23. The Gore® Septal Occluder medical device was not and is not accused by AGA of infringement in the Minnesota Action.

24. The Minnesota Action has been pending for over nine months and has advanced into fact discovery with significant document production by the parties (scheduled to be substantially complete by June 22), and is about to enter the claim construction or *Markman* process.

2. GORE® SEPTAL OCCLUDER MEDICAL DEVICE

25. Gore has invested and continues to invest substantial resources to develop life-saving technology. Such technologies include septal occluders, including the Gore® Septal Occluder medical device. The GORE® HELEX Septal Occluder and the new Gore® Septal Occluder medical device are separate products that each require separate FDA approval and have different structures. The Gore® Septal Occluder medical device is not commercially available in the United States at this time, and the U.S. Food & Drug Administration has not approved the Gore® Septal Occluder medical device for sale in this country.

26. From March 31 to April 2, 2011, a conference entitled the 8th International Workshop on Interventional Pediatric Cardiology was held in Milan, Italy (the "Milan Conference"). Several AGA representatives, including CEO John Barr, attended the Milan conference. AGA had a large presence at the conference and sponsored a trade show booth.

27. On April 1, 2011, during the Milan conference, Dr. M. Carminati gave a presentation that described a next generation or 5-wire septal occluder, being developed by Gore to an audience of hundreds of attendees. The next generation or 5-wire septal occluder, referred to in Dr. Carminati's presentation, is the Gore® Septal Occluder medical device.

28. On June 10, 2011, the Gore® Septal Occluder medical device received its "CE" mark, European regulatory approval that is required for commercial sales in Europe.

29. On June 15, 2011, Dr. Lars Sondergaard implanted the Gore® Septal Occluder medical device in a patient at Rigshospital, Copenhagen, Denmark. The Gore® Septal Occluder medical device was implanted into a 50 year old patient to treat a patent foramen ovale (PFO) defect in his heart.

30. On June 16, 2011, Dr. Sondergaard implanted two additional Gore® Septal Occluder medical devices in patients, again at Rigshospital, Copenhagen, Denmark. In a four year old child, the Gore® Septal Occluder medical device was implanted for fenestrated fontan closure in the heart. In a 44 year old patient, the Gore® Septal Occluder medical device was implanted to treat a PFO defect in the heart.

31. Attempts by Defendant AGA to interrupt, prevent or limit Gore's activities relating to the Gore® Septal Occluder medical device will cause or are likely to cause Gore substantial injury and harm.

3. AGA'S ATTEMPTS TO INJECT THE GORE® SEPTAL OCCLUDER MEDICAL DEVICE INTO THE MINNESOTA ACTION

32. On April 7, 2011, after the Milan Conference, AGA's litigation counsel in the Minnesota Action sent an e-mail to Gore's litigation counsel confirming that AGA was and is aware of the Milan Conference presentation and asked to obtain litigation discovery from Gore relating to that device.

33. On April 11, 2011, AGA served its Second Set of Requests for Production of Documents and Things on Gore in the Minnesota Action seeking, among other things, discovery on the Gore® Septal Occluder medical device.[1] For example, AGA's Document Request No. 31 sought:

> All documents and things relating to each version of a Gore five-wire occluder frame design, including without limitation the "5 Wire Occluder Frame

[1] AGA refers to the Gore® Septal Occluder medical device as the "Five-Wire occluder."

designed for optimal closure," as demonstrated, described or disclosed at any conference, presentation or meeting since 2009, including documents and things sufficient to describe the structure and operation of each such design.

34. On May 6, 2011, AGA served an "amended" Rule 30(b)(6) Deposition Notice of Gore, which added new topic 16, as follows:

> The structure, function and operation of the Gore Five-Wire Occluder Device prior to implantation, during implantation, and after implantation.

35. On May 11, 2011, Gore served its objections to the discovery requests and refused to provide the requested documents and things relating to the Gore® Septal Occluder medical device. The Gore® Septal Occluder medical device was not included in AGA's infringement contentions; it was not, and is not, part of the Minnesota Action.

36. Also on May 11, 2011, AGA's counsel in the Minnesota Action requested an "immediate" meet and confer to discuss Gore's refusal to provide the requested discovery on the Gore® Septal Occluder medical device.

37. On May 12, 2011, the parties held a meet and confer to discuss various discovery issues. AGA's counsel again requested discovery regarding the Gore® Septal Occluder medical device. AGA requested that Gore agree to a waiver of any possible laches defense that Gore might raise in a potential future patent infringement action brought by AGA against the Gore® Septal Occluder medical device.

38. On May 23, 2011, counsel for AGA sent counsel for Gore an email again indicating that AGA still sought information on the Gore® Septal Occluder medical device and it would seek a court ruling as to whether Gore would have to disclose the information to AGA.

39. On May 31, 2011, counsel for AGA and Gore again met and conferred regarding various discovery disputes. During this process, AGA's litigation counsel confirmed that it was seeking a stipulation from Gore waiving any possible laches defense that Gore might raise in a

potential future patent infringement action brought by AGA against the Gore® Septal Occluder medical device.

40. On June 3, 2011, AGA served its Fifth Set of Requests for Production of Documents and Things on Gore in the Minnesota Action seeking, among other things, discovery on the Gore® Septal Occluder medical device. For example, AGA's Document Request No. 47 sought:

> To the extent not already produced, all documents and things relating to … the 5-Wire Septal Occluder, including analyses, communications, correspondence, discussions, evaluations, investigations, memoranda, meeting minutes, reports, statements, studies, or tests.

41. On information and belief, AGA has sought discovery regarding the Gore® Septal Occluder medical device in the Minnesota Action in an attempt to show that the Gore® Septal Occluder medical device could also be accused of infringement in the Minnesota Action. On information and belief, AGA would seek to enjoin patient access to Gore® Septal Occluder medical devices in a future patent infringement action.

42. The Gore® Septal Occluder medical device has not infringed and does not infringe, either directly or indirectly, any valid and enforceable claim of the '552 or '738 patents, either literally or under the doctrine of equivalents. However, as a result of AGA's past litigious conduct against Gore and its implied threats to accuse the Gore® Septal Occluder medical device as an infringement, as described above, a substantial controversy exists between the parties which is of sufficient immediacy and reality to warrant declaratory relief. Absent a declaration of non-infringement and/or invalidity of the claims of the '552 and '738 patents, AGA will continue to threaten Gore, *e.g.*, with the assertion of the '552 or '738 patents against the Gore® Septal Occluder medical device, as a means to intimidate Gore and the doctors seeking to implant the medical device, and thereby cause Gore irreparable injury and damage.

43. Because the structures of the GORE® HELEX Septal Occluder and Gore® Septal Occluder medical device differ, the issues in the Minnesota Action regarding the GORE® HELEX Septal Occluder differ from the issues presented here regarding the Gore® Septal Occluder medical device. Additionally, the '552 patent is not part of the Minnesota Action even though AGA contends it too covers septal occluder technology (including its own AMPLATZER® line of products).

44. This is an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT I

Declaratory Judgment of Non-Infringement of the Claims of the '552 Patent

45. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-44 of this Complaint as if fully set forth herein.

46. The Gore® Septal Occluder medical device has not infringed and does not infringe, directly or indirectly, any valid and enforceable claim of the '552 patent, either literally or under the doctrine of equivalents.

47. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

48. A judicial declaration that Gore does not infringe any claim of the '552 patent is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore® Septal Occluder medical device. Gore is entitled to a declaration and judgment that its Gore® Septal Occluder medical device does not infringe any claim of the '552 patent.

COUNT II

Declaratory Judgment of Patent Invalidity of the Claims of the ’552 Patent

49. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-48 of this Complaint as if fully set forth herein.

50. The ’552 patent claims are invalid for failure to meet the conditions of patentability and/or otherwise comply with one or more of 35 U.S.C. §§ 100 *et seq*., 101, 102, 103 and 112.

51. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

52. A judicial declaration that the ’552 patent claims are invalid for failure to comply with one or more of the requirements of Title 35 of the United States Code is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore® Septal Occluder medical device. Gore is entitled to a declaration and judgment that the ’552 patent claims are invalid under the Patent Act, 35 U.S.C. § 100, *et seq.*

COUNT III

Declaratory Judgment of Non-Infringement of the Claims of the ’738 Patent

53. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-52 of this Complaint as if fully set forth herein.

54. The Gore® Septal Occluder medical device has not infringed and does not infringe, directly or indirectly, any valid and enforceable claim of the ’738 patent, either literally or under the doctrine of equivalents.

55. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

56. A judicial declaration that Gore does not infringe any claim of the ’738 patent is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore® Septal Occluder medical device. Gore is entitled to a declaration and judgment that its Gore® Septal Occluder medical device does not infringe any claim of the ’738 patent.

COUNT IV

Declaratory Judgment of Patent Invalidity of the Claims of the ’738 Patent

57. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-56 of this Complaint as if fully set forth herein.

58. The ’738 patent claims are invalid for failure to meet the conditions of patentability and/or otherwise comply with one or more of 35 U.S.C. §§ 100 *et seq*., 101, 102, 103 and 112.

59. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

60. A judicial declaration that the ’738 patent claims are invalid for failure to comply with one or more of the requirements of Title 35 of the United States Code is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore® Septal Occluder medical device. Gore is entitled to a

declaration and judgment that the ’738 patent claims are invalid under the Patent Act, 35 U.S.C. § 100, *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Gore respectfully requests that the Court enter judgment in favor of Gore granting the following relief:

(i) A declaration that the Gore® Septal Occluder medical device has not infringed and does not infringe any valid and enforceable claim of the ’552 patent;

(ii) A declaration that the ’552 patent claims are invalid for failure to meet the condition for patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 100 *et seq*., 101, 102, 103 and 112;

(iii) A declaration that the Gore® Septal Occluder medical device has not infringed and does not infringe any valid and enforceable claim of the ’738 patent;

(iv) A declaration that the ’738 patent claims are invalid for failure to meet the condition for patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 100 *et seq*., 101, 102, 103 and 112;

(v) A declaration that Gore has the right to manufacture and market the Gore® Septal Occluder medical device without any threat or other interference whatsoever against Gore by AGA, based on or arising out of the ownership of the ’552 patent and/or the ’738 patent;

(vi) An injunction against AGA and its officers, agents, servants, employees, attorneys, and others in active concert or participation with them from asserting infringement or instituting or continuing any legal action for infringement of the

’552 patent or the ’738 patent against Gore or its manufacturers, distributors, customers or end users of their products;

(vii) An order declaring that this is an exceptional case and awarding Gore its costs, expenses, disbursements and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules and common law;

(viii) An order awarding pre-judgment and post-judgment interest on all damages, attorneys’ fees, expenses, and costs awarded to Gore; and

(ix) Such other and further relief as the Court may deem just and proper.

JURY DEMAND

In accordance with Rule 38 of the Federal Rules of Civil Procedure and Rule 38.1 of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Plaintiff Gore respectfully demands a jury trial of all issues triable to a jury in this action.

ASHBY & GEDDES

/s/ Steven J. Balick

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Dated: June 16, 2011

EXHIBIT 1

US005725552A

United States Patent [19]

Kotula et al.

[11] Patent Number: 5,725,552

[45] Date of Patent: Mar. 10, 1998

[54] **PERCUTANEOUS CATHETER DIRECTED INTRAVASCULAR OCCLUSION DEVICES**

[75] Inventors: **Frank Kotula**, Maple Grove; **Kurt Amplatz**; **Curtis Amplatz**, both of St. Paul, all of Minn.

[73] Assignee: **AGA Medical Corporation**, Golden Valley, Minn.

[21] Appl. No.: **647,712**

[22] Filed: **May 14, 1996**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 272,335, Jul. 8, 1994.

[51] **Int. Cl.**[6] **A61B 17/08**

[52] **U.S. Cl.** **606/213**; 606/151

[58] **Field of Search** 606/191–200, 606/213, 151, 1

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"Transcatheter Closure of Heart Defects: Role of Buttoned Devices" from pp. 349–369 Transcatheter Therapy in Pediatric Cardiology—1993.

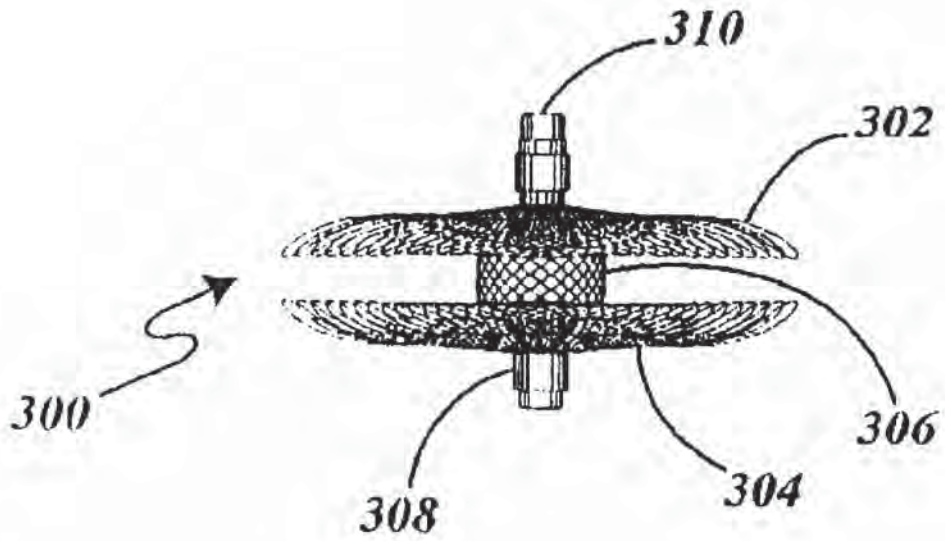
Primary Examiner—Glenn K. Dawson

Attorney, Agent, or Firm—Haugen & Nikolai, P.A.

[57] **ABSTRACT**

The present invention provides a method of forming a medical device and medical devices which can be formed in accordance with the method. In one embodiment, the method includes the steps of a) providing a metal fabric formed of a plurality of strands formed of a metal which can be heat treated to substantially set a desired shape; b) deforming the metal fabric to generally conform to a surface of a molding element; c) heat treating the metal fabric in contact with the surface of the molding element to substantially set the shape of the fabric in its deformed state; and d) removing the metal fabric from contact with the molding element. The resulting metal fabric will define a medical device which can be collapsed for passage through a catheter or the like for deployment in a channel of a patient's body. Medical devices made in accordance with this method can have varying structures.

12 Claims, 15 Drawing Sheets



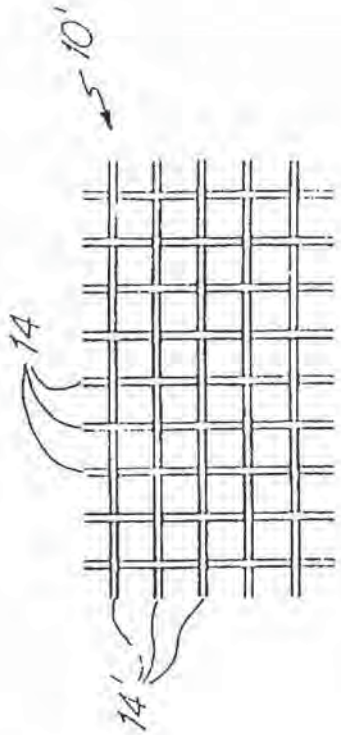


Fig. 1B

Fig. 1A

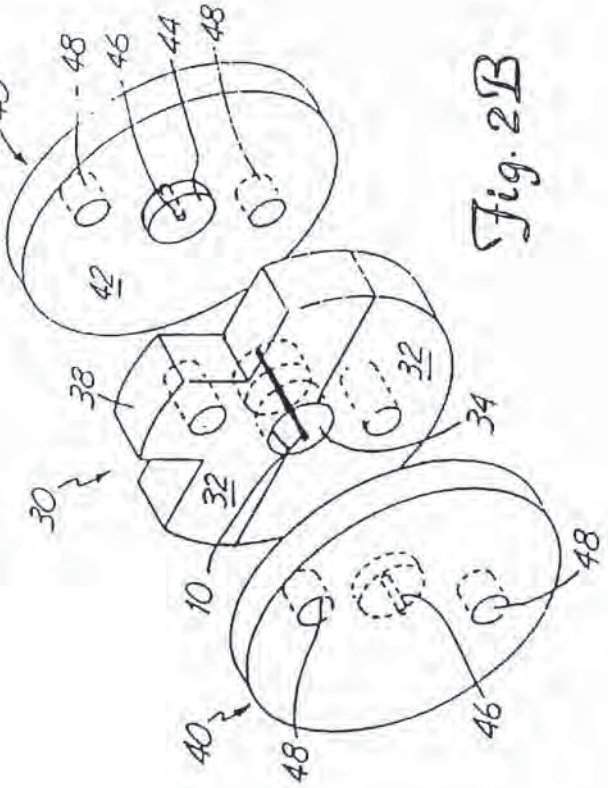

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Fig. 2B

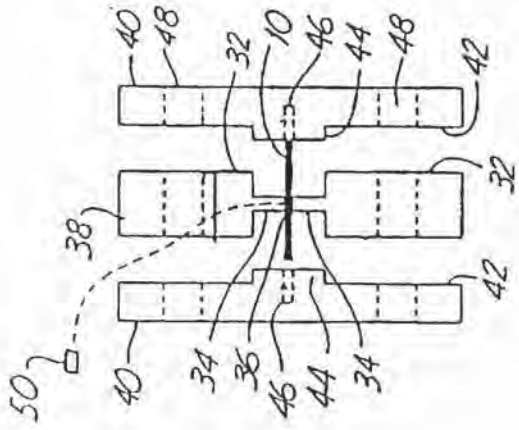
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Fig. 2A

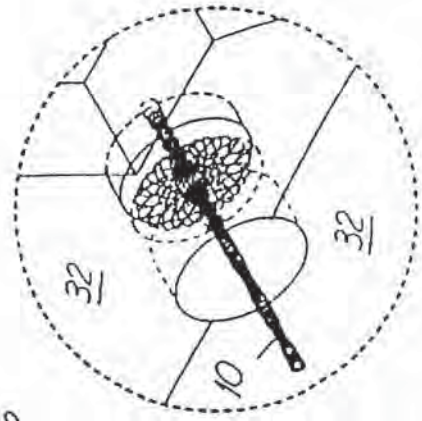


Fig. 3B

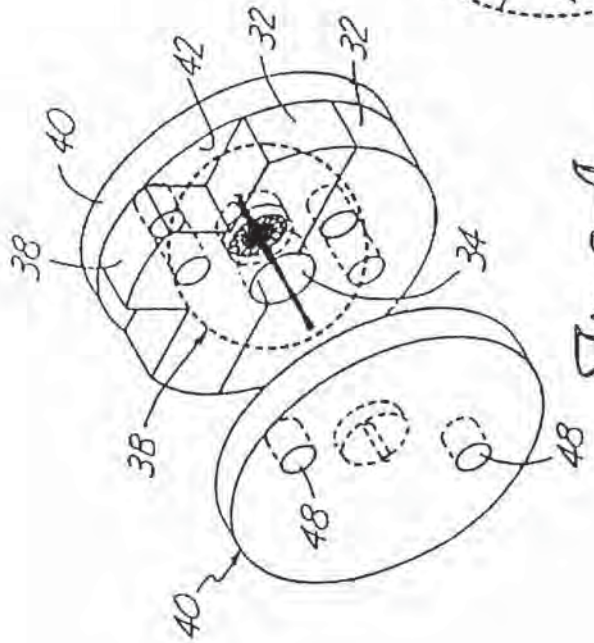


Fig. 3A

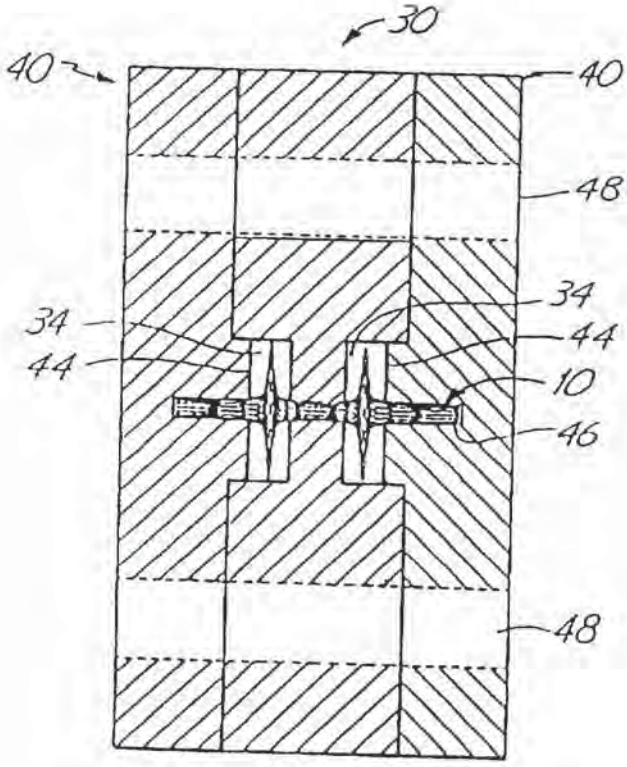


Fig. 4

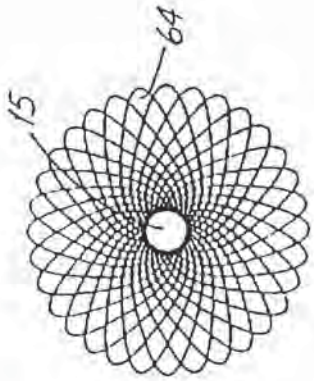


Fig. 5B

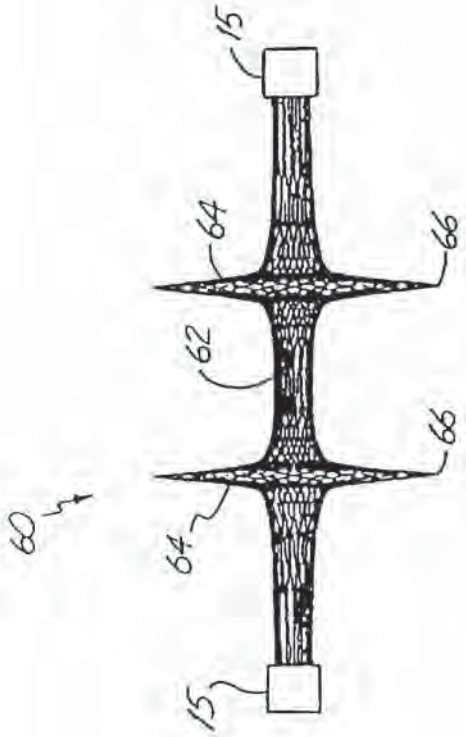


Fig. 5A

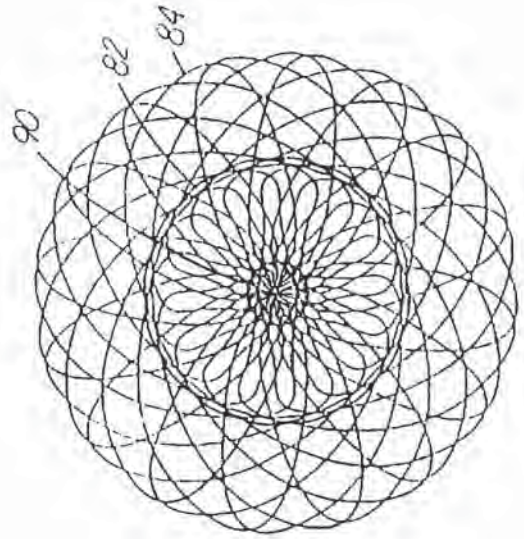


Fig. 6B

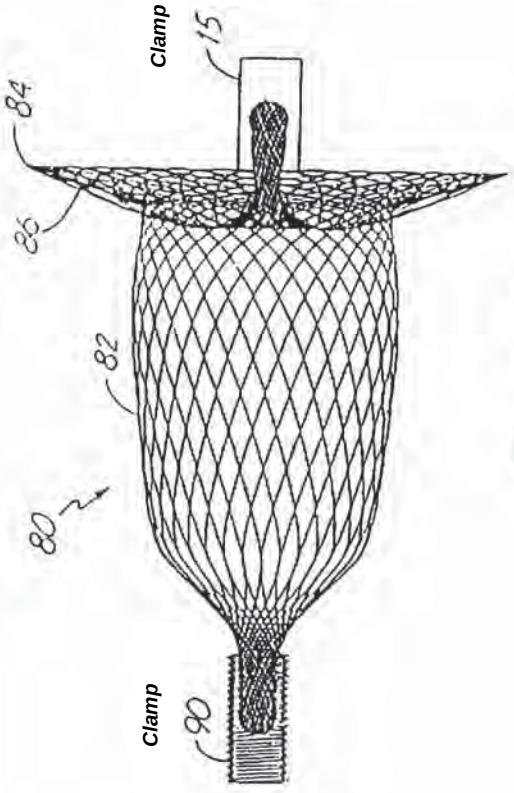


Fig. 6A

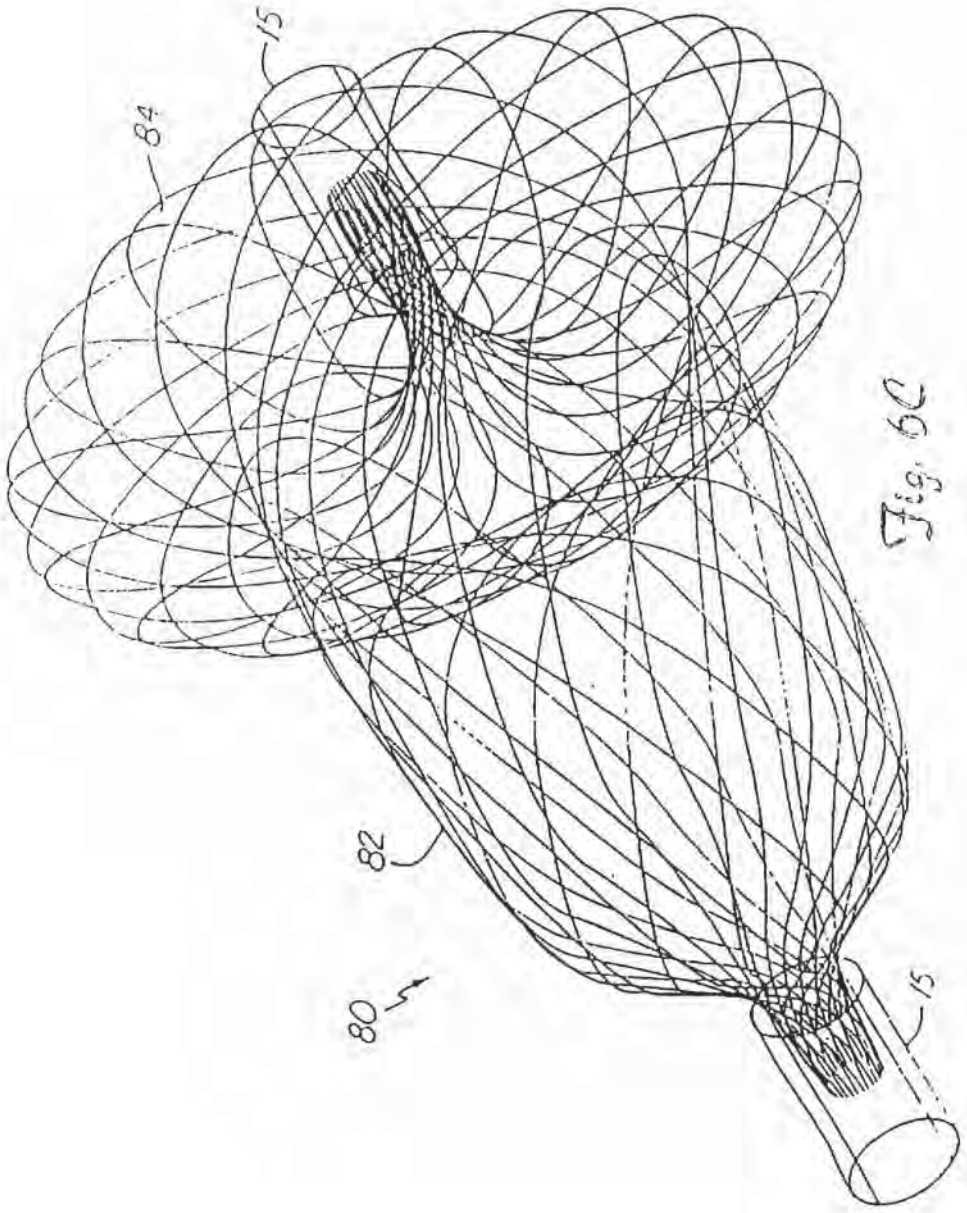


Fig. 6C

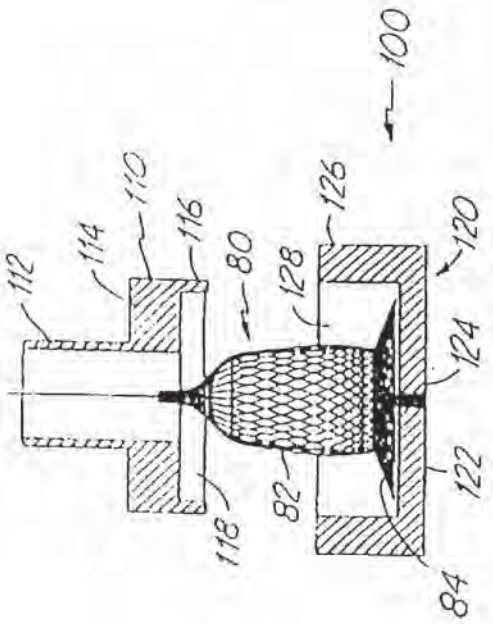

100
110
114
112
116
80
126
128
120
124
122
82
118
84

Fig. 7

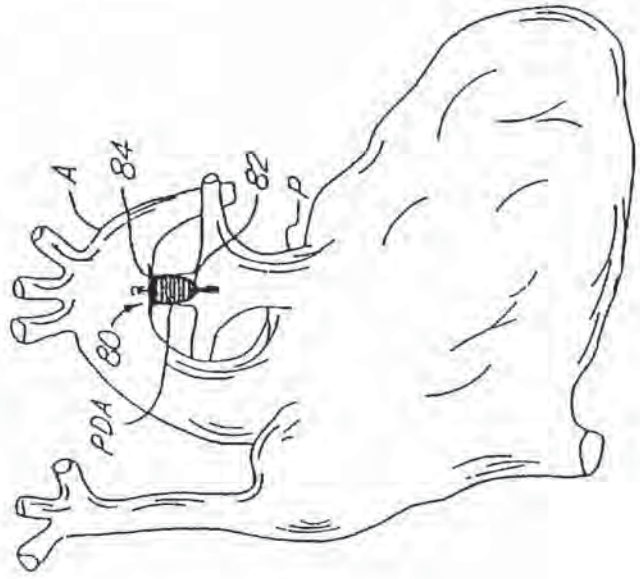

A
84
82
P
80
PDA

Fig. 8

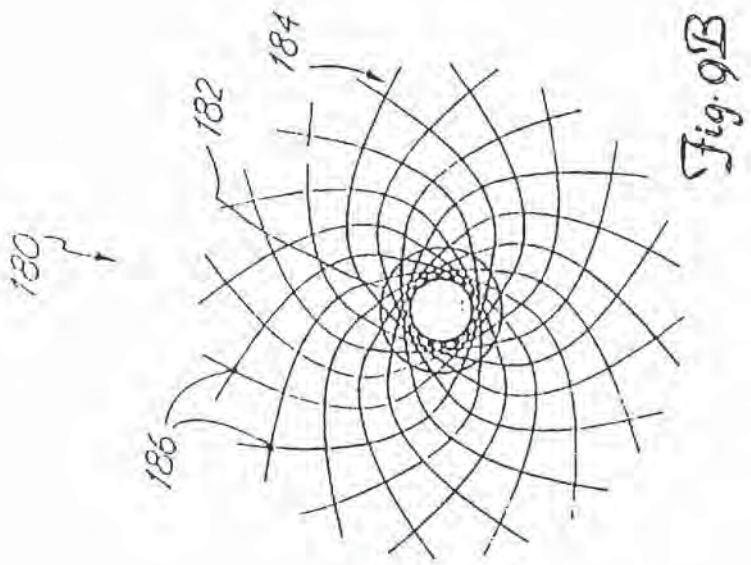


Fig. 9B

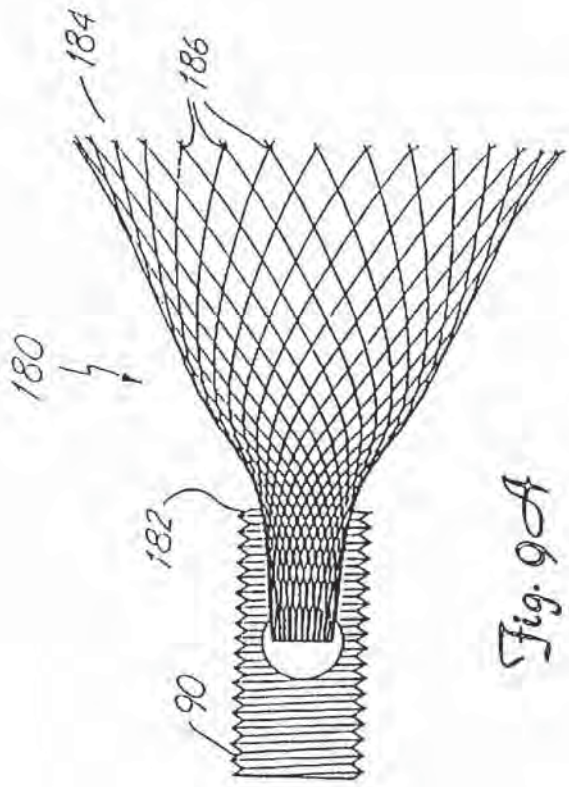


Fig. 9A

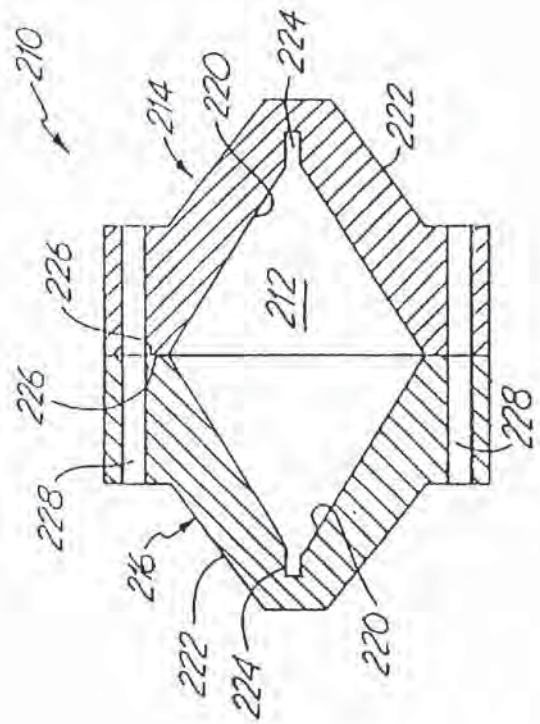


Fig. 10B

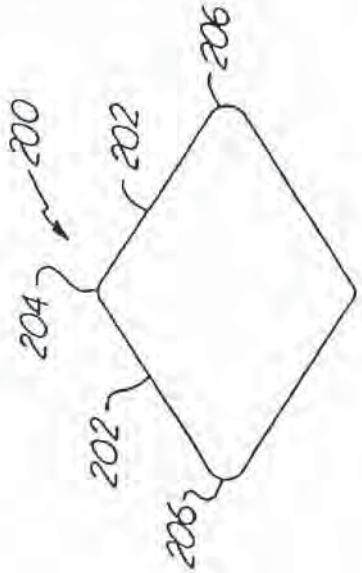


Fig. 10A

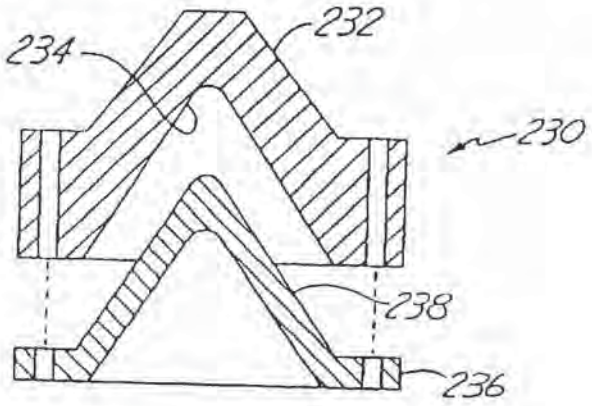


Fig. 10 C

Fig.11

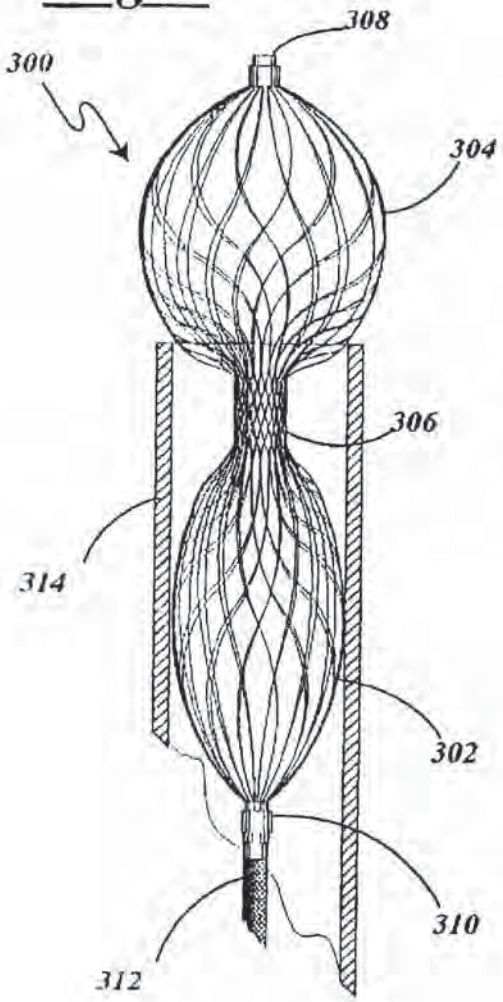


Fig.12

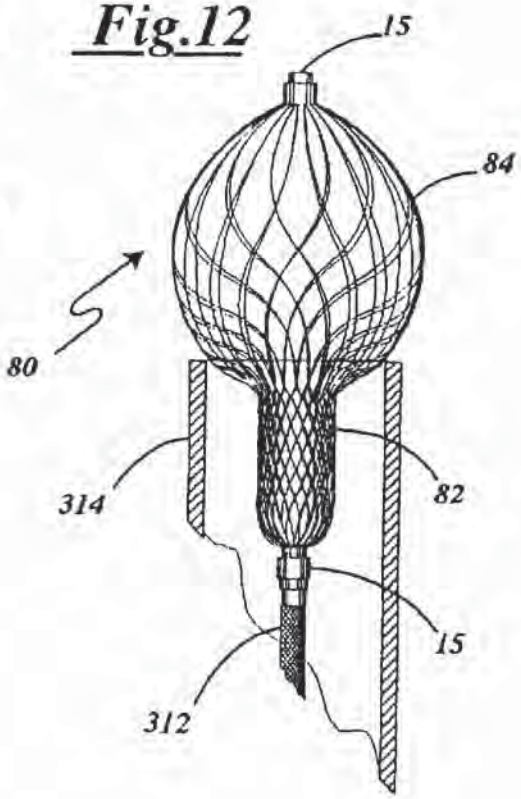


Fig.13

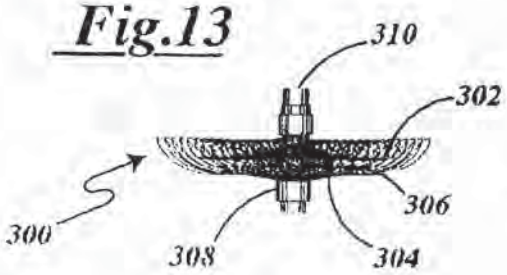


Fig.14

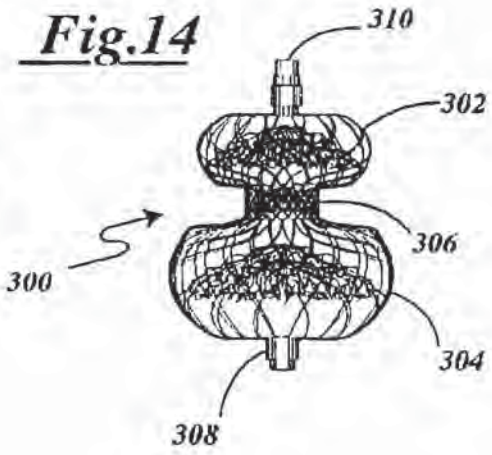


Fig.15

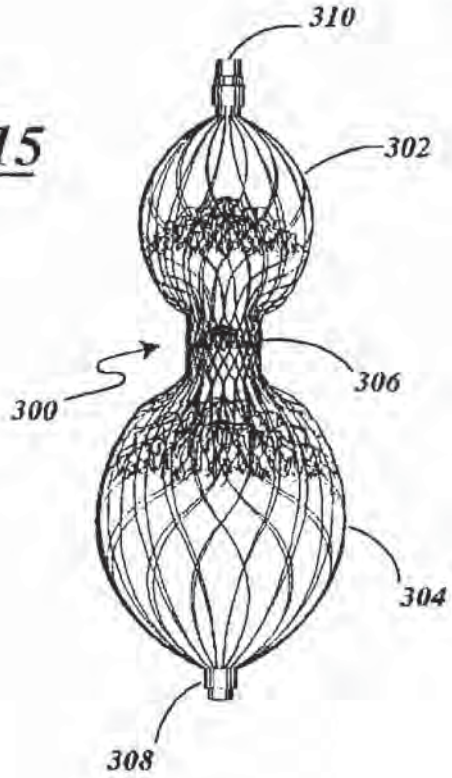


Fig.16

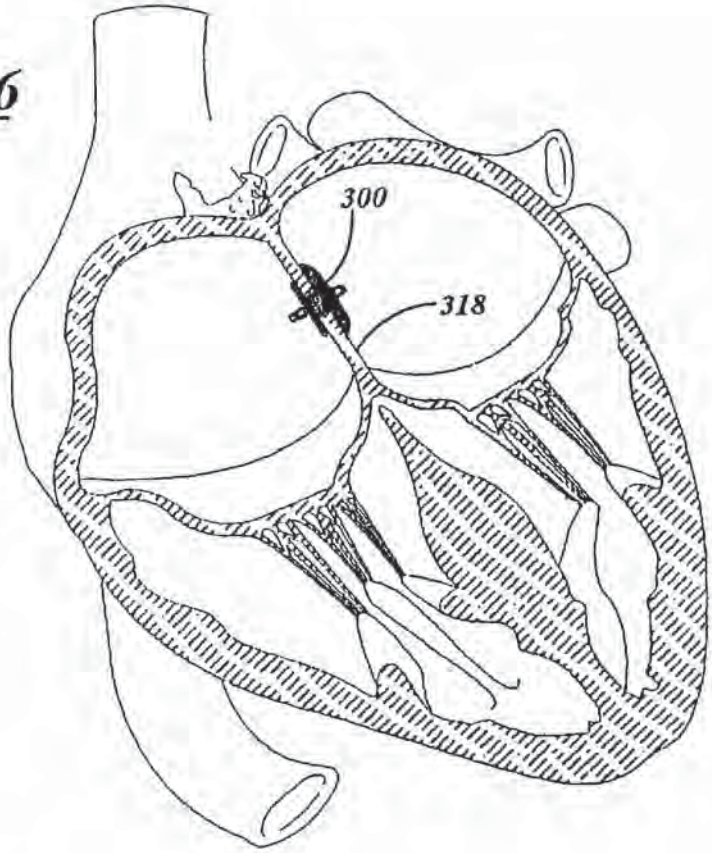


Fig.17

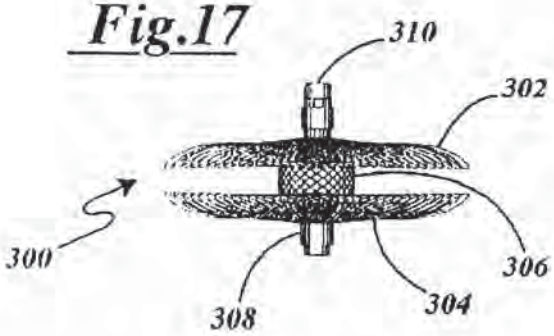
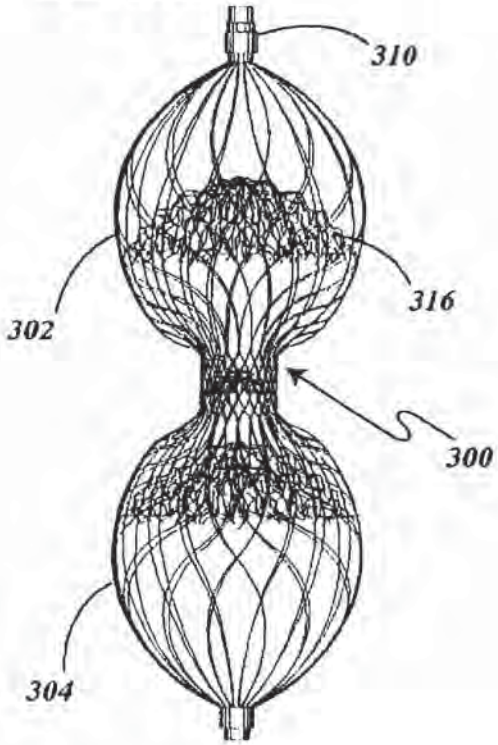


Fig.18



PERCUTANEOUS CATHETER DIRECTED INTRAVASCULAR OCCLUSION DEVICES

The present application is a Continuation-In-Part of application Ser. No. 08/272,335, filed on Jul. 8, 1994, and entitled "METHOD OF FORMING MEDICAL DEVICES; INTRAVASCULAR OCCLUSION DEVICES".

BACKGROUND OF TEE INVENTION

I. Field of the Invention

The present invention generally relates to intravascular devices for treating certain medical conditions and, more particularly, relates to intravascular occlusion devices for Atrial Septal Defects (ASD) and Patent Ductus Arteriosus (PDA) treatment. The devices made in accordance with the invention are particularly well suited for delivery through a catheter or the like to a remote location in a patient's vascular system or in analogous vessels within a patient's body.

II. Description of the Related Art

A wide variety of intravascular devices are used in various medical procedures. Certain intravascular devices, such as catheters and guidewires, are generally used simply to deliver fluids or other medical devices to specific locations within a patient's body, such as a selective site within the vascular system. Other, frequently more complex, devices are used in treating specific conditions, such as devices used in removing vascular occlusions or for treating septal defects and the like.

In certain circumstances, it may be necessary to occlude a patient's vessel, such as to stop blood flow through an artery to a tumor or other lesion. Presently, this is commonly accomplished simply by inserting, for example, Ivalon particles (a trade name for vascular occlusion particles) and short sections of coil springs into a vessel at a desired location. These "embolization agents" will eventually become lodged in the vessel, frequently floating downstream of the site at which they are released before blocking the vessel. This procedure is often limited in its utility, in part, due to the inability to precisely position the embolization agents.

Balloon catheters similar to that disclosed by Landymore et al. in U.S. Pat. No. 4,836,204 have been used by physicians to temporarily occlude a septal defect until the patient stabilizes enough for open heart surgical techniques. Detachable balloon catheters are also used to block patients' vessels. When using such a catheter, an expandable balloon is carried on a distal end of a catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place.

Such balloon embolization is also prone to certain safety problems, though. For example, if the balloon is not filled enough, it will not be firmly fixed in the vessel and may rotate or drift downstream within the vessel to another location, much like the loose embolization agents noted above. In order to avoid this problem, physicians may overfill the balloons; it is not uncommon for balloons to rupture and release the resin into the patient's bloodstream.

Mechanical embolization devices, filters and traps have been proposed in the past, some of which are disclosed in King et al., U.S. Pat. No. 3,874,388; Das, U.S. Pat. No.

5,334,217; and Marks, U.S. Pat. No. 5,108,420. The devices disclosed are pre-loaded into the introducer or delivery catheter and are not easily loadable by the physician. Further, during deployment of these devices, recapture into the delivery catheter is difficult if not impossible, thereby limiting the effectiveness of these devices.

Also, even if some of these devices prove to be effective occluders, they also tend to be rather expensive and time-consuming to manufacture. For example, some intravascular blood filters are formed of a plurality of specially-shaped legs which are adapted to fill the vessel and dig into the vessel walls. In making most such filters, the legs must be individually formed and then painstakingly attached to one another, frequently requiring attachment by hand, to assemble the final filter. Not only does this take significant skilled manpower, and hence increase the costs of such devices, the fact that each item must be made by hand tends to make quality control more difficult. This same difficulty and expense of manufacturing is not limited to such filters, but is experienced in many other intravascular devices as well.

When using these devices to occlude an ASD, the pressure and therefore the chance of dislodgment of the device increases with the square of the size of the communication. Consequently, these devices have to have a very large retention skirt. Often times, the position of the ASD dictates the size of the retention skirt. Hence, there is a need for an ASD occluder which may be made with a relatively small retention skirt. Also, the shape of the prior devices (for example squares, triangles, pentagons, hexagons and octagons) require a larger contact area, having corners which extend to the free wall of the atria. Each time the atria contracts (approximately 100,000 times per day), internal wires within the prior art devices are bent creating structural fatigue fractures in approximately 30 percent of all cases. Furthermore, the previous devices require a French 14-16 introducing catheter, making it impossible to treat children affected with cogentital defects with these devices.

Accordingly, it would be advantageous to provide a reliable embolization device which is both easy to deploy through a 6-7 French catheter and which can be accurately placed in a vessel. It would also be desirable to provide a recoverable device for deployment in a vessel in a patient's body which is both economical and yields consistent, reproducible results.

SUMMARY OF THE INVENTION

The present invention provides a reliable intravascular occlusion device which may be formed to treat, for example, Atrial Septal Defects (hereinafter ASD) and Patent Ductus Arteriosus (hereinafter PDA). When forming these intravascular devices from a resilient metal fabric a plurality of resilient strands is provided, with the wires being formed by braiding to create a resilient material which can be heat treated to substantially set a desired shape. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the braided fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The braided fabric so treated defines an expanded state of a medical device which can be deployed through a catheter into a channel in a patient's body.

Further embodiments of the present invention also provide specific shapes for medical devices which may be made in accordance with the present invention to address predetermined medical procedures. Such devices of the invention are formed of a braided metal fabric and have an expanded configuration and a collapsed configuration. In use, a guide catheter can be positioned in a channel in a patient's body and advanced to position the distal end of the catheter adjacent a treatment site for treating a physiological condition. A medical device, formed in a predetermined shape, and made in accordance with the process outlined above, can be collapsed and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon, due to its memory property it will tend to substantially return to its expanded state adjacent the treatment site. In accordance with a first of these embodiments, a generally elongate medical device has a generally tubular middle portion and a pair of expanded diameter portions, with one expanded diameter portion positioned at either end of the middle portion. In another embodiment, the medical device is generally bell-shaped, having an elongate body having a tapered first end and a larger second end, the second end presenting a fabric disc which will be oriented generally perpendicular to an axis of a channel when deployed therein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1A** and **1B** each depict a metal fabric suitable for use with the invention;

FIG. **2A** is exploded side view of a molding element having inserted a length of a metal fabric suitable for use in forming a medical device in accordance with the invention;

FIG. **2B** is an exploded perspective view of the molding element shown in FIG. **2A**;

FIG. **3A** is a perspective view showing the molding element of FIGS. **2A** and **2B** in a partially assembled state;

FIG. **3B** is a close-up view of a portion of the highlighted area of FIG. **3A** showing the compression of the metal fabric in one of the molding element's cavities;

FIG. **4** is a cross-sectional view showing the molding element of FIGS. **2A** and **2B** in an assembled state, and having the metal fabric formed within the molding elements cavities;

FIG. **5A** is a side view of a medical device in accordance with the invention;

FIG. **5B** is an end view of a medical device in accordance with the invention;

FIGS. **6A–6C** are a side view, an end view and a perspective view, respectively, of a medical device in accordance with another embodiment of the invention;

FIG. **7** is a side, cross sectional view of a molding element suitable for forming the medical device shown in FIGS. **6A–6C**;

FIG. **8** is a schematic illustration showing the device of FIGS. **6A–6C** deployed in a central shunt of a patient's vascular system;

FIG. **9A** is a side view of a medical device in accordance with another alternate preferred embodiment;

FIG. **9B** is an end view of the medical device shown in FIG. **9A**;

FIG. **10A** is a side view of one molding element suitable for forming the embodiment of FIGS. **9A** and **9B**;

FIG. **10B** is a cross-sectional view of another molding element suitable for forming the embodiment of FIGS. **9A** and **9B**;

FIG. **10C** is a cross-sectional view of still another molding element suitable for forming the embodiment of FIGS. **9A** and **9B**;

FIG. **11** is an enlarged, partial sectional view of an ASD device shown stretched and partially extending out from the lumen of a delivery catheter;

FIG. **12** is a partial sectional view of a PDA device of the type shown in FIGS. **6a–6c**, wherein the PDA device is shown stretched and partially extending out from the lumen of a delivery catheter;

FIG. **13** is an enlarged side elevational view of an ASD device, shown in its pre-shaped configuration;

FIG. **14** is a side elevational view of the ASD device of FIG. **13**, shown slightly stretched and filled with polyester fibers;

FIG. **15** is a side elevational view of the ASD device of FIG. **13**, shown stretched and filled with polyester fibers;

FIG. **16** is a partial sectional side elevational view of the ASD device of FIG. **13** shown positioned within an ASD of a patient's heart;

FIG. **17** is an enlarged side elevational view of an alternate ASD device, shown in its pre-shaped configuration; and

FIG. **18** is a side elevational view of the ASD device of FIG. **16**, shown stretched and filled with polyester fibers.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a percutaneous catheter directed intravascular occlusion device for use in shunts in patients' bodies, such as vascular channels, urinary tracts, biliary ducts and the like. In forming a medical device via the method of the invention, a metal fabric **10** is provided. The fabric is formed of a plurality of wire strands having a predetermined relative orientation between the strands. FIGS. **1A** and **1B** illustrate two examples of metal fabrics which are suitable for use in the method of the invention.

In the fabric of FIG. **1A**, the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid. Such tubular braids are well known in the fabric arts and find some applications in the medical device field as tubular fabrics, such as in reinforcing the wall of a guiding or diagnostic catheter. As such braids are well known, they need not be discussed at length here.

The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) may be adjusted as desired for a particular application. For example, if the medical device to be formed is to be used to occlude the channel in which it is placed, the pitch and pick of the fabric will tend to be higher than if the device is simply intended to filter bodily fluid passing therethrough.

For example, in using a tubular braid such as that shown in FIG. **1A** to form a device such as that illustrated in FIGS. **5A** and **5B**, a tubular braid of about 4 mm in diameter with a pitch of about 50° and a pick of about 74 (per linear inch) would seem suitable for fabricating devices used in occluding channels on the order of about 2 mm to about 4 mm in inner diameter, as detailed below in connection with the embodiment of FIGS. **5A** and **5B**.

FIG. **1B** illustrates another type of fabric which is suitable for use in the method of the invention. This fabric is a more

conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like. In the woven fabric shown in FIG. 1B, there are also two sets **14** and **14'** of generally parallel strands, with one set of strands being oriented at an angle, e.g. generally perpendicular (having a pick of about 90°), with respect to the other set. As noted above, the pitch and pick of this fabric (or, in the case of a knit fabric, the pick and the pattern of the knit, e.g. Jersey or double knits) may be selected to optimize the desired properties of the final medical device.

The wire strands of the metal fabric used in the present method should be formed of a material which is both resilient and which can be heat treated to substantially set a desired shape. Materials which are suitable for this purpose include a cobalt-based low thermal expansion alloy referred to in the field as Elgeloy, nickel-based high temperature high-strength "superalloys" commercially available from Haynes International under the trade name Hastelloy, nickel-based heat treatable alloys sold under the name Incoloy by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wires is that the wires retain a suitable amount of the deformation induced by the molding surface (as described below) when subjected to a predetermined heat treatment.

One class of materials which meet these qualifications are so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

One particularly preferred shape memory alloy for use in the present method is nitinol, an approximately stoichiometric alloy of nickel and titanium, which may also include other minor amounts of other metals to achieve desired properties. NiTi alloys such as nitinol, including appropriate compositions and handling requirements, are well known in the art and such alloys need not be discussed in detail here. For example, U.S. Pat. Nos. 5,067,489 (Lind) and 4,991,602 (Amplatz et al.), the teachings of which are incorporated herein by reference, discuss the use of shape memory NiTi alloys in guidewires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic—they are said to be "superelastic" or "pseudoelastic". This elasticity will help a device of the invention return to a present expanded configuration for deployment.

In forming a medical device in keeping with the invention, an appropriately sized piece of the metal fabric is cut from the larger piece of fabric which is formed, for example, by braiding wire strands to form a long tubular braid. The dimensions of the piece of fabric to be cut will depend, in large part, upon the size and shape of the medical device to be formed therefrom.

When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual wire strands will tend to return to their heat-set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more economical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device, as noted below.

In such untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of braid cut to form the device are constrained relative to one another. One method which has proven to be useful to prevent the braid from unraveling is to clamp the braid at two locations and cut the braid to leave a length of the braid having clamps (**15** in FIG. **2**) at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps **15** will hold the ends of the cut braid together and prevent the braid from unraveling.

Alternatively, one can solder, braze, weld or otherwise affix the ends of the desired length together (e.g. with a biocompatible cementitious organic material) before cutting the braid. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder.

The same problems present themselves when a flat sheet of fabric such as the woven fabric shown in FIG. 1B is used. With such a fabric, the fabric can be inverted upon itself to form a recess or depression and the fabric can be clamped about this recess to form an empty pocket (not shown) before the fabric is cut. If it is desired to keep the fabric in a generally flat configuration, it may be necessary to weld the junctions of the strands together adjacent the periphery of the desired piece of fabric before that piece is cut from the larger sheet. So connecting the ends of the strands together will prevent fabrics formed of untreated shape memory alloys and the like from unraveling during the forming process.

Once an appropriately sized piece of the metal fabric is obtained, the fabric is deformed to generally conform to a surface of a molding element. As will be appreciated more fully from the discussion below in connection with FIGS. **2–10**, so deforming the fabric will reorient the relative positions of the strands of the metal fabric from their initial order to a second, reoriented configuration. The shape of the molding element should be selected to deform the fabric into substantially the shape of the desired medical device.

The molding element can be a single piece, or it can be formed of a series of mold pieces which together define the surface to which the fabric will generally conform. The molding element can be positioned within a space enclosed by the fabric or can be external of such a space, or can even be both inside and outside such a space.

In order to illustrate one example of how such a mold may be configured and how it may be used in accordance with the method of the invention, reference will be had to FIGS. **2–5**. In FIGS. **2–4**, the molding element **20** is formed of a number of separate pieces which can be attached to one another to complete the molding element **20**. In using such a multi-piece molding element, the mold can be assembled about the cut length of fabric **10**, thereby deforming the fabric to generally conform to the desired surface (or surfaces) of the molding element.

In the molding element illustrated in FIGS. **2–4**, the metal fabric **10** is deformed to generally conform to a surface of the molding element **20**, the molding element comprising a center section **30** and a pair of end plates **40**. Turning first to the center section **30**, the center section is desirably formed of opposed halves **32**, **32** which can be moved away from one another in order to introduce the metal fabric **10** into the mold. Although these two halves **32**, **32** are shown in the

drawings as being completely separated from one another, it is to be understood that these halves could be interconnected, such as by means of a hinge or the like, if so desired. The opposed halves of the molding element **20** shown in the drawings of FIGS. **2** and **3** each include a pair of semi-circular recesses opposed on either side of a ridge defining a generally semi-circular opening. When the two halves are assembled in forming the device, as best seen in FIG. **3**, the semi-circular openings in the opposed halves **32**, **32** mate to define a generally circular forming port **36** passing through the center section **30**. Similarly, the semi-circular recesses in the two halves together form a pair of generally circular central recesses **34**, with one such recess being disposed on either face of the center section.

The overall shape and dimensions of the center section can be varied as desired; it is generally the size of the central recesses **34** and the forming port **36** which will define the size and shape of the middle of the finished device, as explained below. If so desired, each half **32** may be provided with a manually graspable projection **38**. In the embodiment shown in the drawings, this projection **38** is provided at a location disposed away from the abutting faces of the respective halves. Such a manually graspable projection **38** will simply enable an operator to more easily join the two halves to define the recesses **34** and forming port **36**.

The center section is adapted to cooperatively engage a pair of end plates **40** for forming the desired device. In the embodiment shown in FIGS. **2** and **3**, the center section **30** has a pair of flat outer faces **39** which are each adapted to be engaged by an inner face **42** of one of the two end plates **40**. Each end plate includes a compression disk **44** which extends generally laterally inwardly from the inner face **42** of the end plate. This compression disk **44** should be sized to permit it to be received within one of the central recesses **34** on either face of the center section **30**. For reasons explained more fully below, each compression disk **44** includes a cavity **46** for receiving an end of the length of the metal fabric **10**.

One or more channels **48** for receiving bolts and the like may also be provided through each of the end plates and through the center section **30**. By passing bolts through these channels **48**, one can assemble the molding element **20** and retain the metal fabric in the desired shape during the heat treatment process, as outlined below.

In utilizing the molding element **20** shown in FIGS. **2–4**, a length of the metal fabric **10** can be positioned between the opposed halves **32** of the center section **30**. In the drawings of the molding element **20** of FIGS. **2–4**, the metal fabric **10** is a tubular braid such as that illustrated in FIG. **1A**. A sufficient length of the tubular braid should be provided to permit the fabric to conform to the molding surface, as explained below. Also, as noted above, care should be taken to secure the ends of the wire strands defining the tubular braid in order to prevent the metal fabric from unraveling.

A central portion of the length of the metal braid may be positioned within one of the two halves of the forming port **36** and the opposed halves **32** of the center section may be joined to abut one another to restrain a central portion of the metal braid within the central forming port **36** through the center section.

The tubular braid will tend to have a natural, relaxed diameter which is defined, in large part, when the tubular braid is formed. Unless the tubular braid is otherwise deformed, when the wire strands are in their relaxed state they will tend to define a generally hollow tube having the predetermined diameter. The outer diameter of the relaxed braid may be, for example, about 4 mm. The relative size of the forming port **36** in the central section **30** of the molding element and the natural, relaxed outer diameter of the tubular braid may be varied as desired to achieve the desired shape of the medical device being formed.

In the embodiment shown in FIGS. **2** and **3**, the inner diameter of the forming port **36** is optimally slightly less than the natural, relaxed outer diameter of the tubular braid **10**. Hence, when the two halves **32**, **32** are assembled to form the center section **30**, the tubular braid **10** will be slightly compressed within the forming port **36**. This will help ensure that the tubular braid conforms to the inner surface of the forming port **36**, which defines a portion of the molding surface of the molding element **20**.

If so desired, a generally cylindrical internal molding section (not shown) may also be provided. This internal molding section has a slightly smaller diameter than the inner diameter of the forming port **36**. In use, the internal molding section is placed within the length of the metal fabric, such as by manually moving the wire strands of the fabric apart to form an opening through which the internal molding section can be passed. This internal molding section should be positioned within the tubular braid at a location where it will be disposed within the forming port **36** of the center section when the molding element is assembled. There should be a sufficient space between the outer surface of the interior molding section and the inner surface of the forming port **36** to permit the wire strands of the fabric **10** to be received therebetween.

By using such an internal molding section, the dimensions of the central portion of the finished medical device can be fairly accurately controlled. Such an internal molding section may be necessary in circumstances where the natural, relaxed outer diameter of the tubular braid **10** is less than the inner diameter of the forming port **36** to ensure that the braid conforms to the inner surface of that forming port. However, it is not believed that such an internal molding section would be necessary if the natural, relaxed outer diameter of the braid were larger than the inner diameter of the forming port **36**.

As noted above, the ends of the tubular braid should be secured in order to prevent the braid from unraveling. Each end of the metal fabric **10** is desirably received within a cavity **46** formed in one of the two end plates **40**. If a clamp (**15** in FIG. **2**) is used, the clamp may be sized to be relatively snugly received within one of these cavities **46** in order to effectively attach the end of the fabric to the end plate **40**. The end plates can then be urged toward the center section **30** and toward one another until the compression disk **44** of each end plate is received within a central recess **34** of the center section **30**. The molding element may then be clamped in position by passing bolts or the like through the channels **48** in the molding element and locking the various components of the molding element together by tightening a nut down onto such a bolt (not shown).

As best seen in FIG. **3A**, when an end plate is urged toward the center section **30**, this will compress the tubular braid **10** generally along its axis. When the tubular braid is in its relaxed configuration, as illustrated in FIG. **1A**, the wire strands forming the tubular braid will have a first, predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis, as illustrated in FIG. **4**. When the fabric is so deformed, the relative orientation of the wire strands of the metal fabric will change. When the molding element is finally assembled, the

metal fabric will generally conform to the molding surface of this element.

In the molding element **20** shown in FIGS. **2–4**, the molding surface is defined by the inner surface of the forming port, the inner surfaces of the central recess **34** and the faces of the compression disks **44** which are received within the recesses **34**. If an internal molding section is used, the cylindrical outer surface of that section may also be considered a part of the molding surface of the molding element **20**. Accordingly, when the molding element **20** is completely assembled the metal fabric will tend to assume a somewhat "dumbbell"-shaped configuration, with a relatively narrow center section disposed between a pair of bulbous, perhaps even disk-shaped end sections, as best seen in FIG. **4**.

It should be understood that the specific shape of the particular molding element **20** shown in FIGS. **2–4** is intended to produce one useful medical device in accordance with the present method, but that other molding elements having different shape configurations could also be used. If a more complex shape is desired, the molding element may have more parts, but if a simpler shape is being formed, the molding element may have even fewer parts. The number of parts in a given molding element and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device as the molding element must define a molding surface to which the metal fabric will generally conform.

Accordingly, the specific molding element **20** shown in FIGS. **2–4** is simply intended as one specific example of a suitable molding element for forming one particular useful medical device. Additional molding elements having different designs for producing different medical devices are explained below in connection with, e.g., FIGS. **8** and **10**. Depending on the desired shape of the medical device being formed, the shape and configuration of other specific molding elements can be readily designed by those of ordinary skill in the art.

Once the molding element **20** is assembled with the metal fabric generally conforming to a molding surface of that element, the fabric can be subjected to a heat treatment while it remains in contact with that molding surface. This heat treatment will depend in large part upon the material of which the wire strands of the metal fabric are formed, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface.

The time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire stands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a "superelastic" or "pseudoelastic" phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal when in its austenitic phase can be set. This will tend to "set" the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

Suitable heat treatments of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils, for example, are used in a number of medical applications, such as in forming the coils commonly carried around distal lengths of guidewires. A wide body of knowledge exists for forming nitinol in such medical devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention.

Briefly, though, it has been found that holding a nitinol fabric at about 500° C. to about 550° C. for a period of about 1 to about 30 minutes, depending on the softness or harness of the device to be made, will tend to set the fabric in its deformed state, i.e. wherein it conforms to the molding surface of the molding element. At lower temperatures the heat treatment time will tend to be greater (e.g. about one hour at about 350° C.) and at higher temperatures the time will tend to be shorter (e.g. about 30 seconds at about 900° C.). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors which will be well known to those skilled in this field.

Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. In the present invention, this can be accomplished by, for example, hooking electrodes to the clamps **15** carried at either end of the metal fabric illustrated in FIG. **5**. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire molding element to the desired heat treating temperature in order to heat the metal fabric to the desired temperature.

After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in a deformed state. When the molding element **20** illustrated in FIGS. **2–4** is used, the bolts (not shown) may be removed and the various parts of the molding element may be disassembled in essentially the reverse of the process of assembling the molding element. If an internal molding section is used, this molding section can be removed in much the same fashion that it is placed within the generally tubular metal fabric in assembling the molding element **20**, as detailed above.

FIGS. **5A** and **5B** illustrate one embodiment of a medical device **60** which may be made using the molding element **20** of FIGS. **2–4**. As discussed below, the device of FIG. **5** is particularly well suited for use in occluding a channel within a patient's body and these designs have particular advantages in use as vascular occlusion devices.

The vascular occlusion device **60** of FIG. **5A** includes a generally tubular middle portion **62** and a pair of expanded diameter portions **64**. One expanded diameter portion is disposed at either end of the generally tubular middle portion **62**. In the embodiment shown in FIGS. **5A** and **5B**, the expanded diameter portions **64** include a ridge **66** positioned about midway along their lengths.

The relative sizes of the tubular middle section and the expanded diameter portions can be varied as desired. In this particular embodiment, the medical device is intended to be used as a vascular occlusion device to substantially stop the flow of blood through a patient's blood vessel. When the device **60** is deployed within a patient's blood vessel, as detailed below, it will be positioned within the vessel such that its axis generally coincides with the axis of the vessel. The dumbbell-shape of the present device is intended to limit the ability of the vascular occlusion device **60** to turn at an angle with respect to the axis of the blood vessel to

ensure that it remains in substantially the same position in which the operator deploys it within the vessel.

In order to relatively strongly engage the lumen of the blood vessel, the maximum diameter of the expanded diameter portions **64** (which occurs along the middle ridge **66** in this embodiment) should be selected so that it is at least as great as the diameter of the lumen of the vessel in which it is to be deployed, and is optimally slightly greater than that diameter. When it is deployed within the patient's vessel, the vascular occlusion device **60** will engage the lumen at two spaced-apart locations. The device **60** is desirably longer along its axis than the dimension of its greatest diameter. This will substantially prevent the vascular occlusion device **60** from turning within the lumen at an angle to its axis, essentially preventing the device from becoming dislodged and tumbling along the vessel with blood flowing through the vessel.

The relative sizes of the generally tubular middle portion **62** and expanded diameter portion **64** of the vascular occlusion device **60** can be varied as desired for any particular application. For example, the outer diameter of the middle portion **62** may range between about one quarter and about one third of the maximum diameter of the expanded diameter portions **64** and the length of the middle portion **62** may comprise about 20% to about 50% of the overall length of the device. Although these dimensions are suitable if the device **60** is to be used solely for occluding a vascular vessel, it is to be understood that these dimensions may be varied if the device is to be used in other applications, such as where the device is intended to be used simply as a vascular filter rather than to substantially occlude the entire vessel or where the device is deployed in a different channel in a patient's body.

The aspect ratio (i.e., the ratio of the length of the device over its maximum diameter or width) of the device **60** illustrated in FIGS. **5**A and **5**B is desirably at least about 1.0, with a range of about 1.0 to about 3.0 being preferred and an aspect ratio of about 2.0 being particularly preferred. Having a greater aspect ratio will tend to prevent the device from rotating generally perpendicularly to its axis, which may be referred to as an end over end roll. So long as the outer diameter of the expanded diameter portions **64** of the device is large enough to seat the device fairly securely against the lumen of the channel in which the device is deployed, the inability of the device to turn end over end will help keep the device deployed precisely where it is positioned within the patient's vascular system or in any other channel in the patient's body. Alternatively, having expanded diameter portions which have natural, relaxed diameters substantially larger than the lumen of the vessels in which the device is deployed should also suffice to wedge the device into place in the vessel without undue concern being placed on the aspect ratio of the device.

The pick and pitch of the metal fabric **10** used in forming the device **60**, as well as some other factors such as the number of wires employed in a tubular braid, are important in determining a number of the properties of the device. For example, the greater the pick and pitch of the fabric, and hence the greater the density of the wire strands in the fabric, the stiffer the device will be. Having a greater wire density will also provide the device with a greater wire surface area, which will generally enhance the tendency of the device to occlude a blood vessel in which it is deployed. This thrombogenicity can be either enhanced by, e.g. a coating of a thrombolytic agent, or abated, e.g. by a coating of a lubricious, anti-thrombogenic compound.

When the device is deployed in a patient's vessel, thrombi will tend to collect on the surface of the wires. By having a greater wire density, the total surface area of the wires will be increased, increasing the thrombotic activity of the device and permitting it to relatively rapidly occlude the vessel in which it is deployed. It is believed that forming the occlusion device **60** from a 4 mm diameter tubular braid having a pick of at least about 40 and a pitch of at least about 30° will provide sufficient surface area to substantially completely occlude a blood vessel of 2 mm to about 4 mm in inner diameter in a suitable period of time. If it is desired to increase the rate at which the device **60** occludes the vessel in which it is deployed, any of a wide variety of known thrombotic agents can be applied to the device.

FIGS. **6**A–**6**C illustrate an alternative embodiment of a medical device in accordance with the present invention. This device **80** has a generally bell-shaped body **82** and an outwardly extending forward end **84**. One application for which this device is particularly well suited is occluding defects known in the art as central shunts or patent ductus arteriosus (PDA). PDA is essentially a condition wherein two blood vessels, most commonly the aorta and pulmonary artery adjacent the heart, have a shunt between their lumens. Blood can flow directly between these two blood vessels through the shunt, compromising the normal flow of blood through the patient's vessels.

As explained more fully below in connection with FIG. **8**, the bell-shaped body **82** is adapted to be deployed within the shunt between the vessels, while the forward end **84** is adapted to be positioned within the aorta to help seat the body in the shunt. The sizes of the body **82** and the end **84** can be varied as desired for differently sized shunts. For example, the body may have a diameter along its generally cylindrical middle **86** of about 10 mm and a length along its axis of about 25 mm. In such a device, the base **88** of the body may flare generally radially outward until it reaches an outer diameter equal to that of the forward end **84**, which may be on the order of about 20 mm in diameter.

The base **88** desirably flares out relatively rapidly to define a shoulder tapering radially outwardly from the middle **86** of the body. When the device is deployed in a vessel, this shoulder will abut the lumen of the vessels being treated with higher pressure. The forward end **84** is retained within the vessel and urges the base **88** of the body open to ensure that the shoulder engages the wall of the vessel to prevent the device **80** from becoming dislodged from within the shunt.

As detailed above, in making a device of the invention it is desirable to attach the ends of the wire strands forming the metal fabric **10** to one another to prevent the fabric from unraveling. In the illustrations of FIGS. **6**A–**6**C, a clamp **15** is used to tie together the ends of the wire strands adjacent the front end **84** of the device. It is to be understood that this clamp **15** is simply a schematic illustration, though, and that the ends could be attached in other ways, such as by welding, soldering, brazing, use of a biocompatible cementitious material or in any other suitable fashion.

The rearward ends of the wire strands are shown as being attached to one another by an alternative clamping means **90**. This clamp **90** serves the same purpose as the schematically illustrated clamp **15**, namely to interconnect the ends of the wires. However the clamp **90** also serves to connect the device **80** to a delivery system (not shown). In the embodiment shown, the clamp **90** is generally cylindrical in shape and has a recess for receiving the ends of the wires to substantially prevent the wires from moving relative to one another, and a threaded outer surface. The threaded outer surface is adapted to be received within a cylindrical recess

(not shown) on a distal end of a delivery device and to engage the threaded inner surface of the delivery device's recess.

The delivery device (not shown) can take any suitable shape, but desirably comprises an elongate, flexible metal shaft having such a recess at its distal end. The delivery device can be used to urge the PDA occlusion device **80** through the lumen of a catheter for deployment in a channel of the patient's body, as outlined below. When the device is deployed out the distal end of the catheter, the device will still be retained by the delivery device. Once the proper position of the device **80** in the shunt is confirmed, the shaft of the delivery device can be rotated about its axis to unscrew the clamp **90** from the recess in the delivery means.

By keeping the PDA device **80** attached to the delivery means, the operator could still retract the device for repositioning if it is determined that the device is not properly positioned in the first attempt. This threaded attachment will also allow the operator to control the manner in which the device **80** is deployed out of the distal end of the catheter. As explained below, when the device exits the catheter it will tend to resiliently return to a preferred expanded shape which is set when the fabric is heat treated. When the device springs back into this shape, it may tend to act against the distal end of the catheter, effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp **90** can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled and the operator can control the deployment to ensure proper positioning.

APDA occlusion device **80** of this embodiment of the invention can advantageously be made in accordance with the method outlined above, namely deforming a metal fabric to generally conform to a molding surface of a molding element and heat treating the fabric to substantially set the fabric in its deformed state. FIG. **7** shows a molding element **100** which may be suitable for forming a PDA occlusion device **80** such as that shown in FIGS. **6A–6C**.

The molding element **100** generally comprises a body portion **110** and an end plate **120**. The body portion **110** is adapted to receive and form the body **82** of the device **80** while the end plate is adapted to compress against the metal fabric to form the forward end **84**. The body portion **110** includes an elongate, generally tubular central segment **112** which is sized to receive the elongate body **82** of the device. The central segment **112** of the molding element **100** optimally has an internal diameter slightly less than the natural, relaxed outer diameter of the tubular braid of which the device is formed. This compression of the braid will help yield devices with reproducibly sized bodies **82**. The forward end of the body portion **110** includes a back plate **114** which has a generally annular sidewall **116** depending downwardly therefrom. The sidewall defines a recess **118** which is generally circular in shape.

The end plate **120** of the molding element **100** has a generally disc-shaped face **122**, which desirably has a clamp port **124** approximately centered therein for receiving a clamp **15** attached to the metal fabric, as noted above. The end plate also has an annular sidewall **126** which extends generally upwardly from the face **122** to define a generally cylindrical recess **128** in the end plate **120**. The sidewall **116** of the body portion **110** is sized to be received within the recess **128** of the end plate.

In use, the metal fabric is placed in the molding element and the body portion **110** and the end plate **120** are brought toward one another. The inner face of the back plate **114** will engage the fabric and tend to urge it under compression generally radially outwardly. The fabric will then be enclosed generally within the recess **118** of the body portion and will generally conform to the inner surface of that recess. If one prevents the entire clamp **15** from passing through the clamp port **124**, the fabric will be spaced slightly away from the inner surface of the face **122**, yielding a slight dome shape in the forward end **84** of the device, as illustrated in FIGS. **6**. Although the illustrated embodiment includes such a dome-shaped forward end, it is to be understood that the forward end may be substantially flat (except for the clamp **15**), which can be accomplished by allowing the clamp to be received entirely within the clamp port **124** in the end plate.

Once the fabric is compressed in the molding element **100** so that it generally conforms to the molding surface of the molding element, the fabric can be subjected to a heat treatment such as is outlined above. When the molding element is opened again by moving the body portion **110** and the end plate **120** away from one another again, the fabric will generally retain its deformed, compressed configuration. The device can then be collapsed, such as by urging the clamps **15**, **90** generally axially away from one another, which will tend to collapse the device toward its axis. The collapsed device **80** can then be passed through a catheter for deployment in a channel in a patient's vascular system.

FIG. **8** schematically illustrates how a medical device **80** generally as outlined above can be used to occlude a patent ductus arteriosus. In this case, there is a shunt, referred to as a PDA above, which extends between a patient's aorta A and the pulmonary artery P. The device **80** can be passed through the PDA, such as by keeping the device collapsed within a catheter (not shown), and the forward end **84** of the device can be allowed to elastically expand to substantially recover its thermally set, "remembered" shape from the heat treatment process, such as by urging the device distally to extend beyond the distal end of the catheter. This forward end **84** should be larger than the lumen of the shunt of the PDA.

The device can then be retracted so that the forward end **84** engages the wall of the pulmonary artery P. If one continues to retract the catheter, the engagement of the device with the wall of the PDA will tend to naturally pull the body portion **82** of the device from the catheter, which will permit the body portion to return to its expanded configuration. The body portion should be sized so that it will frictionally engage the lumen of the PDA's shunt. The device **80** will then be held in place by the combination of the friction between the body portion and the lumen of the shunt and the aortic blood pressure against the forward end **84** of the device. Over a relatively short period of time, thrombi will form in and on the device **80** and the thrombi will occlude the PDA. Those skilled in the art will appreciate that in order to speed up the occlusion of the PDA or ASD device, the device may be coated with a suitable thrombogenic agent, filled with a polyester fiber or braided with an increased number of wire strands.

FIGS. **9A** and **9B** are a side view and an end view, respectively, of yet another embodiment of the present invention. This device **180** can be used for a variety of applications in a patient's blood vessels. For example, if a fabric having a relatively high pick (i.e. where the wire density is fairly great) is used in making the device, the device can be used to occlude blood vessels. In other applications, it may serve as a filter within a channel of a

patient's body, either in a blood vessel or in another channel, such as in a urinary tract or biliary duct. In order to further enhance or reduce the device's tendency to occlude the vessel, depending on the application of the device a suitable known anti-thrombogenic coating may be applied to the device.

This filter **180** has a generally conical configuration, tapering generally radially outwardly from its rearward end **182** to its forward end **184**. A length of the device adjacent its forward end is adapted to engage the walls of a lumen of a channel. The maximum diameter of the filter device **180** is therefore at least as large as the inner diameter of the channel in which it is to be positioned so that at least the forward end will engage the wall of the vessel to substantially lock the device in place.

Having a series of unsecured ends **185** of the wire strands adjacent the forward end of the device will assist in seating the device in the channel because the ends of the wires will tend to dig into the vessel wall slightly as the forward end of the device urges itself toward its fully expanded configuration within the vessel. The combination of the friction between the outwardly urging forward end of the device and the tendency of the wire ends to dig into the vessel walls will help ensure that the device remains in place where it is deployed rather than floating freely within a vessel to reach an undesired location.

The method in which the device **180** of the invention is deployed may vary depending on the nature of the physiological condition to be treated. For example, in treating an arterio-venous fistula, the device may be carefully positioned, as described above, to occlude the flow of blood at a fairly specific location. In treating other conditions (e.g. an arterio-venous malformation), however, it may be desired to simply release a number of these devices upstream of the malformation in a vessel having a larger lumen and simply allow the devices to drift from the treatment site to lodge in smaller vessels downstream.

The decision as to whether the device **180** should be precisely positioned at an exact location within the channel in a patient's body or whether it is more desirable to allow the device(s) to float to their final lodging site will depend on the size of the channels involved and the specific condition to be treated. This decision should be left to the individual operator to be made on a case-by-case basis as his or her experience dictates; there is no one right or wrong way to deploy the device **180** without regard to the conditions at hand.

In the embodiment shown in FIGS. **9A** and **9B**, the wall of the device extends generally linearly from a position adjacent the clamp **90** and the other end of the device, approximating a conical shape. Due to the presence of the clamp **90**, though, the end of the device immediately adjacent the clamp may deviate slightly from the cone shape, as indicated in the drawings. Alternatively, the wall may be curved so that the diameter of the device changes more rapidly adjacent the rearward end than it does adjacent its forward end, having an appearance more like a rotation of a parabola about its major axis than a true cone. Either of these embodiments should suffice in occluding a vessel with the device **180**, such as to occlude a vessel.

The ends of the wire strands at the rearward end **182** of the device are secured with respect to one another, such as by means of a threaded clamp **90** such as that described above in connection with FIGS. **6A–6C**. Portions of the wire strands adjacent the forward end **184** may also be secured against relative movement, such as by spot welding wires to one another where they cross adjacent the forward end. Such a spot weld is schematically illustrated at **186** in FIGS. **9A** and **9B**.

In the embodiment illustrated in FIGS. **9**, though, the ends of the wire strands adjacent the forward end **184** in the finished device need not be affixed to one another in any fashion. These strands are held in a fixed position during the forming process to prevent the metal fabric from unraveling before it is made into a finished device. While the ends of the wire strands adjacent the forward end remain fixed relative to one another, they can be heat treated, as outlined above. The heat treatment will tend to fix the shapes of the wires in their deformed configuration wherein the device generally conforms to a molding surface of the molding element. When the device is removed from contact with the molding element, the wires will retain their shape and tend to remain intertwined. Accordingly, when the device is released from contact with the molding element, even if the ends of the wires are released from any constraint the device should still substantially retain its shape.

FIGS. **10A–10C** illustrate three suitable molds for use in forming the filter **180** of FIGS. **9A** and **9B**. In FIG. **10A**, the molding element **200** is a single piece which defines a pair of generally conical portions abutting one another. In another similar embodiment (not shown), the molding element **200** may be generally ovoid, shaped not unlike an American football or a rugby ball. In the embodiment illustrated in FIG. **10A**, though, the molding element is a little bit less rounded. This molding element comprises two conical segments **202** which abut one another at their bases, defining a larger diameter at the middle **204** of the element which can taper relatively uniformly toward the ends **206** of the element **200**.

When the a tubular braid is used in forming this device, the tubular metal fabric may be applied to the molding element by placing the molding element within the tubular braid and clamping the ends of the braid about the molding element before cutting the braid to the desired length. In order to better facilitate the attachment of the clamps **90** to the ends of the tubular braid, the ends **206** of the molding element may be rounded, as shown, rather than tapering to a sharper point at the ends of the molding element. In order to ensure that the braid more closely conforms to the outer surface of the molding element **200**, i.e. the molding element's molding surface, the natural, relaxed diameter of the braid should be less than the maximum diameter of the element, which occurs at its middle **204**. This will place the metal fabric in tension about the middle of the element and, in combination with the clamps at the ends of the braid, cause the braid to generally conform to the molding surface.

FIG. **10B** illustrates an alternative molding element **210** for forming a device substantially as shown in FIGS. **9A** and **9B**. Whereas the molding element **200** is intended to be received within a recess in the metal fabric, such as within the lumen of a length of tubular braid, the molding element **210** has an internal cavity **212** adapted to receive the fabric. In this embodiment, the molding element may comprise a pair of molding sections **214**, **216** and these mold sections may be substantially identical in shape. Each of the molding sections **214**, **216** generally comprise a conical inner surface **220** defined by a wall **222**. Each section also may be provided with a generally cylindrical axial recess **224** for receiving a clamp **15** (or **90**) carried by an end of the metal fabric.

The two molding sections should be readily attached to one another with the larger, open ends **226** of the sections

abutting one another. The mold sections can simply be clamped together, such as by providing a reusable jig (not shown) which can be used to properly position the sections **214, 216** with respect to one another. If so desired, bolt holes **228** or the like may be provided to allow a nut and bolt, or any similar attachment system, to be passed through the holes and attach the sections **214, 216** together.

In use, a suitably sized piece of a metal fabric, optimally a length of a tubular braid, is placed in the recess **212** of the molding element and the two molding sections **214, 216** are urged toward one another. The fabric should have a relaxed axial length longer than the axial length of the recess **212** so that bringing the sections toward one another will axially compress the fabric. This axial compression will tend to urge the wire strands of the braid radially outwardly away from the axis of the braid and toward engagement with the molding surface of the element **210**, which is defined by the surface of the recess **212**.

Once the metal fabric is deformed to generally conform to the molding surface of either molding element **200** or **210**, the fabric can be heat treated to substantially set the shape of the fabric in its deformed state. If molding element **200** is used, it can then be removed from the interior of the metal fabric. If there is sufficient room between the resilient wire strands, the molding element can simply be removed by opening the web of wire strands and pulling the molding element out of the interior of the metal fabric. If molding element **210** is employed, the two molding sections **214, 216** can be moved away from one another and the molded fabric can be retrieved from the recess **212**. Depending on the shape of the molding surface, the resulting formed shape may resemble either a pair of abutting hollow cones or, as noted above, a football, with clamps, welds or the like provided at either end of the shape.

This shape can then be cut into two halves by cutting the wires in a direction generally perpendicular to the shared axis of the cones (or the major axis of the ovoid shape) at a location about midway along its length. This will produce two separate filter devices **180** substantially as illustrated in FIGS. **9**A and **9**B. If the wires strands are to be joined adjacent the forward end of the device (such as by the weldments shown as **186** in FIGS. **9**A and **9**B), this can be done before the conical or ovoid shape is severed into two halves. Much the same net shape could be accomplished by cutting the metal fabric into halves while it is still carried about molding element **200**. The separate halves having the desired shape could then be pulled apart from one another, leaving the molding element ready for forming additional devices.

In an alternative embodiment of this method, the molding element **200** is formed of a material selected to permit the molding element to be destroyed for removal from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material, such as glass. Once the material has been heat treated in contact with the molding surface of the molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The glass shards can then be removed from the enclosure of the metal fabric. The resultant shape can be used in its generally conical shape, or it can be cut into two separate halves to produce a device substantially as shown in FIGS. **9**A and **9**B.

Alternatively, the molding element **200** can be formed of a material which can be chemically dissolved, or otherwise broken down, by a chemical agent which will not substantially adversely affect the properties of the metal wire strands. For example, the molding element can be formed of a temperature-resistant plastic resin which is capable of being dissolved with a suitable organic solvent. The fabric and the molding element can be subjected to a heat treatment to substantially set the shape of the fabric in conformance with the surface of the molding element, whereupon the molding element and the metal fabric can be immersed in the solvent. Once the molding element is substantially dissolved, the metal fabric can be removed and either used in its current shape or cut into separate halves, as outlined above.

Care should be taken to ensure that the material selected to form the molding element is capable of withstanding the heat treatment without losing its shape, at least until the shape of the fabric has been set. For example, the molding element could be formed of a material having a melting point above the temperature necessary to set the shape of the wire strands, but below the melting point of the metal forming the strands. The molding element and metal fabric can then be heat treated to set the shape of the metal fabric, whereupon the temperature can be increased to substantially completely melt the molding element, thereby removing the molding element from within the metal fabric.

It should be understood that the methods outlined immediately above for removing the metal fabric **10** from the molding element **200** can be used in connection with other shapes, as well. Although these methods may not be necessary or desirable if the molding element is carried about the exterior of the metal fabric (such as are elements **30–40** of the molding element **20** of FIGS. **2–4**), if the molding element or some portion thereof is enclosed within the formed metal fabric (such as the internal molding section of the molding element **20**), these methods can be used to effectively remove the molding element without adversely affecting the medical device being formed.

FIG. **10**C illustrates yet another molding element **230** which can be used in forming a medical device such as that illustrated in FIGS. **9**A and **9**B. This molding element comprises an outer molding section **232** defining a tapered inner surface **234** and an inner molding section **236** having an outer surface **238** substantially the same shape as the tapered inner surface **234** of the outer molding section. The inner molding section **236** should be sized to be received within the outer molding section, with a piece of the metal fabric (not shown) being disposed between the inner and outer molding sections. The molding surface of this molding element **230**, to which the fabric will generally conform, can be considered to include both the inner surface **234** of the outer molding section and the outer surface **238** of the inner molding section. This molding element **230** can be used with a metal fabric which is in the form of a tubular braid. If such a fabric is used and a clamp **15** (not shown in this drawing) or the like is provided to connect the ends of the wire strands adjacent one end of the device, a recess (not shown) analogous to the cavity **46** in the face of the compression disk **44** of molding element **20** (FIGS. **2–4**) can be provided for receiving the clamp.

However, the present molding element **230** can be used quite readily with a flat woven piece of metal fabric, such as is illustrated in FIG. **1**B. In using such a fabric, a suitably sized and shaped piece of fabric is cut; in using the molding element **230** to produce a device **180** analogous to that shown in FIGS. **9**A and **9**B, for example, a generally disk-shaped piece of the metal fabric **10'** can be used. The metal fabric is then placed between the two sections **232**.

236 of the molding element and the sections are moved together to deform the fabric therebetween. After heat treatment, the fabric can be removed and will retain substantially the same shape as it had when it was deformed between the two molding sections.

As can be seen by the discussion of the various molding elements **200**, **210** and **230** in FIGS. **10**A–**10**C, it should be clear that a number of different molding elements may achieve essentially the same desired shape. These molding elements may be received entirely within a closed segment of fabric and rely on tension and/or compression of the fabric to cause it to generally conform to the molding surface of the molding element, as with the element **200** of FIG. **10**A. The molding element **210** of FIG. **10**B substantially encloses the fabric within a recess in the mold and relies on compression of the fabric (in this case axial compression of a tubular braid) to deform the fabric to the desired configuration. Finally, the fabric may be compressed between two coating parts of the molding element to deform the fabric, such as between the two sections **232**, **236** of molding element **230** in FIG. **10**C. Any one or more of these techniques may be used in achieving a finished product having a desired shape.

FIGS. **11** and **13**–**15** illustrate alternate preferred embodiment of a medical device in accordance with the present invention for correcting an atrial septal defect (ASD). With reference to FIGS. **13** and **15**, the device **300** in its relaxed, unstretched state has two disks **302** and **304** aligned in spaced relation, linked together by a short cylinder **306**. It is proposed that this device **300** may also be well suited in occluding defects known in the art as patent foraman ovale (hereinafter PFO). ASD is a congenital abnormality of the atrial septum characterized by structural deficiency of the atrial septum. A shunt may be present in the atrial septum, allowing flow between the right and left atriums. In large defects with significant left to right shunts through the defect, the right atrium and right ventricle are volume overloaded and the augmented volume is ejected into a low-resistance pulmonary vascular bed.

Pulmonary vascular occlusive disease and pulmonary atrial hypertension develops in adulthood. Patients with secundum ASD with a significant shunt (defined as a pulmonary blood flow to systemic blood flow ratio of greater than 1.5) are operated upon ideally at five years of age or whenever a diagnosis is made in later years. With the advent of two dimensional echocardiagraphy and Doppler color flow mapping, the exact anatomy of the defect can be visualized. The size of the defect will correspond to the selected size of the ASD device to be used.

The device **300**, shown in its unconfined or relaxed state in FIG. **13**, is adapted to be deployed within the shunt comprising an ASD or a PFO. For exemplary purposes, use of the device **300** in an ASD closure procedure will be described below. Turning first to the constructional features of the device **300**, the ASD occluder **300** is sized in proportion to the shunt to be occluded. In the relaxed orientation, the metal fabric is shaped such that two disk like members **302** and **304** are axially aligned and linked together by a short cylindrical segment **306**. The length of the cylindrical segment **306** preferably approximates the thickness of the atrial septum, and ranges between 2 to 20 mm. The proximal **302** and distal **304** disks preferably have an outer diameter sufficiently larger than the shunt to prevent dislodging of the device. The proximal disk **302** has a relatively flat configuration, whereas the distal disk **304** is cupped towards the proximal end slightly overlapping the proximal disk **302**.

The ends of this braided metal fabric device **300** are welded or clamped together with clamps **308** and **310** as described above to avoid fraying. Of course the ends may alternately be held together by other means readily known to those skilled in the art. The clamp **310** tying together the wire strands at the proximal end also serves to connect the device to a delivery system (see FIG. **11**). In the embodiment shown, the clamp **310** is generally cylindrical in shape and has a recess for receiving the ends of the metal fabric to substantially prevent the wires comprising the woven fabric from moving relative to one another. The clamp **310** also has a threaded surface within the recess. The threaded recess is adapted to receive and engage the threaded distal end of a delivery device **312**.

The ASD occlusion device **300** of this embodiment of the invention can advantageously be made in accordance with the method outlined above. The device **300** is preferably made from a 0.005 inches nitinol wire mesh. The braiding of the wire mesh may be carried out with 28 picks per inch at a shield angle of about 64 degrees using a Maypole braider with **72** wire carriers. The stiffness of the ASD device **300** may be increased or decreased by altering the wire size, the shield angle, the pick size, the number of wire carriers or the heat treatment process.

Those skilled in the art will recognize from the preceding discussion that the cavities of the mold must be shaped consistent with the desired shape of the ASD device. Also, it will be recognized that certain desired configurations may require that portions of the cavities be cammed. FIGS. **17** and **18** illustrate an ASD device having a modified configuration. The proximal disk **302** is a mirror image of distal disk **304**. The distance separating the proximal and distal disks **302** and **304** is less than the length of the cylindrical segment **306**. The cup shape of the disk, as illustrated in FIGS. **13**, **16** and **17**, ensures complete contact between the occlusion device **300** and the atrial septum. As such, a neo endocardium layer of endothelial forms over the occlusion device **300**, thereby reducing the chance of bacterial endocarditis.

Referring next to FIGS. **11**, **14**–**16** and **18** the use of the device will now be discussed in greater detail. The device may be delivered and properly placed using two dimensional echocardiagraphy and Doppler color flow mapping. As indicated above, the delivery device **312** can take any suitable shape, preferably comprising an elongated flexible metal shaft similar to a conventional guidewire. The delivery device **312** is used to advance the ASD occlusion device **300** through the lumen of a small diameter cylindrical tube **314**, such as a delivery catheter, for deployment. The ASD device **300** is loaded into the small diameter cylindrical tube **314** by stretching the same to put it in an elongated condition. The device may be inserted into the lumen of the tube **314** during the procedure or preassembled at a manufacturing facility, in that the devices of the present invention do not take on a permanent set when maintained in a compressed state.

From a femoral vein approach, the delivery catheter or tube **314** is passed across the ASD. The device **300** is advanced through the delivery catheter until the distal end **304** becomes unconstrained on exiting the end of the catheter, whereupon it assumes its disk-like shape in the left atrium. The delivery catheter **314** is then pulled back in the proximal direction across the ASD and the delivery device **312** is likewise pulled in a proximal direction, urging the distal disk **304** against the septum **318**. The delivery catheter **314** is then further pulled away from the septum **318**, allowing the proximal disk **302** to extend out of the delivery catheter **314**, where it resiliently returns to its predefined expanded disk-like shape (see FIG. **15**). In this manner, the

ASD device **300** is positioned such that the distal disk **304** presses against one side of the septum **318** while the proximal disk **302** presses against the other side of the septum **318**. In order to increase its occluding ability, the device can contain polyester fibers **316** (see FIGS. **15** and **18**). In instances where the device is improperly deployed on a first try, the device **300** may be recovered by pulling the deliver device **312** proximally, thereby retracting the device **300** back into the delivery catheter **314** prior to a second attempt at positioning the device **300** relative to the defect.

When the ASD occluding device **300** is properly placed, the physician rotates the delivery device **312**, unscrewing the delivery device **312** from the clamp **310** of the occluding device **300**. The threads on the clamp **310** are such that the rotation of the delivery device **312** unscrews the delivery device **312** from the clamp **310** of the occluding device **300**, rather than merely rotating the occluding device **300**. As noted above in alternate embodiments, the threaded clamp can enable the operator to maintain a hold on the device during deployment, or enables the operator to control the spring action during deployment of the device to ensure proper positioning.

Generally, the method in accordance with the present invention further includes a method of treating a physiological condition of a patient. In accordance with this method, a medical device suitable for treating the condition, which may be substantially in accordance with one of the embodiments outlined above, is selected. For example, if a patent ductus arteriosus is to be treated, the PDA occlusion device **80** of FIGS. **6A–6C** can be selected. Once the appropriate medical device is selected, a catheter may be positioned within a channel in patient's body to place the distal end of the catheter adjacent the desired treatment site, such as immediately adjacent (or even within) the shunt of the PDA.

Medical devices made in accordance with the method of the invention outlined above have a preset expanded configuration and a collapsed configuration which allows the device to be passed through a catheter (see FIG. **12**). The expanded configuration is generally defined by the shape of the medical fabric when it is deformed to generally conform to the molding surface of the molding element. Heat treating the metal fabric substantially sets the shapes of the wire strands in the reoriented relative positions when the fabric conforms to the molding surface. When the metal fabric is then removed from the molding element, the fabric may define a medical device in its preset expanded configuration.

The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter. For example, the devices shown in FIGS. **5A–5B**, **6A–6C**, and **13** may have a relatively elongated collapsed configuration wherein the devices are stretched along their axes (see FIGS. **11** and **12**). This collapsed configuration can be achieved simply by stretching the device generally along its axis, e.g. by manually grasping the clamps **15** and pulling them apart, which will tend to collapse the expanded diameter portions **64** of the device **60** inwardly toward the device's axis. The PDA occlusion device **80** of FIGS. **6** also operates in much the same fashion and can be collapsed into its collapsed configuration for insertion into the catheter by applying tension generally along the axis of the device. In this regard, these devices **60** and **80** are not unlike "Chinese handcuffs", which tend to constrict in diameter under axial tension.

Once the medical device is collapsed and inserted into the catheter, it may be urged along the lumen of the catheter toward the distal end of the catheter. This may be accomplished by using a guidewire or the like to abut against the device and urge it along the catheter. When the device begins to exit the distal end of the catheter, which is positioned adjacent the desired treatment site, it will tend to resiliently return substantially entirely to its preset expanded configuration. Superelastic alloys, such as nitinol, are particularly useful in this application because of their ability to readily return to a particular configuration after being elastically deformed to a great extent. Hence, simply urging the medical device out of the distal end of the catheter tend to properly deploy the device at the treatment site.

Although the device will tend to resiliently return to its initial expanded configuration (i.e. its shape prior to being collapsed for passage through the catheter), it should be understood that it may not always return entirely to that shape. For example, the device **60** of FIG. **5** is intended to have a maximum outer diameter in its expanded configuration at least as large as and preferably larger than, the inner diameter of the lumen in which it is to be deployed. If such a device is deployed in a vessel having a small lumen, the lumen will prevent the device from completely returning to its expanded configuration. Nonetheless, the device would be properly deployed because it would engage the inner wall of the lumen to seat the device therein, as detailed above.

If the device is to be used to permanently occlude a channel in the patient's body, such as the devices **60** and **80** described above may be, one can simply retract the catheter and remove it from the patient's body. This will leave the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means, such as when the, threaded clamp **90** shown in FIGS. **6** and **9** are attached to a distal end of the delivery means, as explained above. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A collapsible medical device, comprising a plurality of metal strands woven into a tubular woven metal fabric having a proximal end and a distal end, each end having a means for securing each end attached to said tubular woven metal fabric, thereby gathering said strands and inhibiting unraveling of the strands, said tubular woven metal fabric having an expanded preset configuration shaped to create an occlusion of an abnormal opening in a body organ, said expanded preset configuration being in a shape of a bell and deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the woven metal fabric having a memory property whereby the medical device tends to return to said expanded preset configuration when unconstrained.

2. The medical device as recited in claim **1**, wherein said means for securing each end has a threaded bore for rotational attachment to a delivery device.

3. The medical device as recited in claim **2**, further including an occluding fiber retained within a hollow central portion formed by said tubular woven fabric.

4. The medical device as recited in claim **1**, wherein the metal fabric is manufactured from an alloy selected from the

group consisting of stainless steel, nickel-titanium, and cobalt-chromium-nickel.

5. The medical device as recited in claim **4**, further including an occluding fiber retained within a hollow central portion formed by said tubular woven fabric.

6. The medical device as recited in claim **1**, further including an occluding fiber retained within a hollow central portion formed by said tubular woven fabric.

7. A collapsible medical device, comprising: a tubular woven metal fabric including a plurality of braided strands and having a proximal end and a distal end, each end having a clamp attached to said metal fabric to thereby gather said strands together and inhibit unraveling of the strands, said metal fabric having a collapsed configuration for delivery through a channel in a patient's body and a generally dumbbell shaped expanded preset configuration for substantially creating an occlusion of an abnormal opening in a body organ, the metal fabric in its expanded configuration having two expanded diameter portions and a reduced diameter portion disposed between the two expanded diameter portions, each expanded diameter portion having an inner and outer wall, wherein the inner wall of at least one of the expanded diameter portions is generally concave.

8. The medical device as recited in claim **7**, further including an occluding fiber retained within a hollow central portion formed by said generally dumbbell shaped expanded configuration.

9. A collapsible medical device, comprising a tubular woven metal fabric including a plurality of braided strands and having a proximal end and a distal end, each end having a clamp attached to said tubular woven metal fabric to thereby gather said strands together and inhibit the strands from unraveling, said tubular woven metal fabric having an expanded preset configuration shaped to create an occlusion of an abnormal opening in a body organ, said expanded preset configuration being deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, wherein the expanded preset configuration comprises two expanded diameter portions and a reduced diameter portion, said reduced diameter portion having a length approximating a thickness of a patient's atrial septum, the woven metal fabric having a memory property whereby the medical device tends to return to said expanded preset configuration when unconstrained.

10. The medical device as recited in claim **9**, wherein said clamp has a threaded bore adapted for rotationally receiving a delivery device.

11. The medical device as recited in claim **9**, further including an occluding fiber contained within a hollow center portion formed by said tubular woven metal fabric.

12. The medical device as recited in claim **9**, wherein the metal fabric is manufactured from an alloy selected from the group consisting of stainless steel, nickel-titanium, and cobalt-chromium-nickel.

* * * * *

EXHIBIT 2

US005944738A

United States Patent [19]

Amplatz et al.

[11] **Patent Number: 5,944,738**

[45] **Date of Patent: Aug. 31, 1999**

[54] **PERCUTANEOUS CATHETER DIRECTED CONSTRICTING OCCLUSION DEVICE**

[75] Inventors: **Kurt Amplatz**, St. Paul; **Michael R. Afremov**, St. Louis Park, both of Minn.

[73] Assignee: **AGA Medical Corporation**, Golden Valley, Minn.

[21] Appl. No.: **09/019,620**

[22] Filed: **Feb. 6, 1998**

[51] **Int. Cl.**[6] **A61B 17/08**

[52] **U.S. Cl.** **606/213**

[58] **Field of Search** 606/213, 151, 606/1, 191–200

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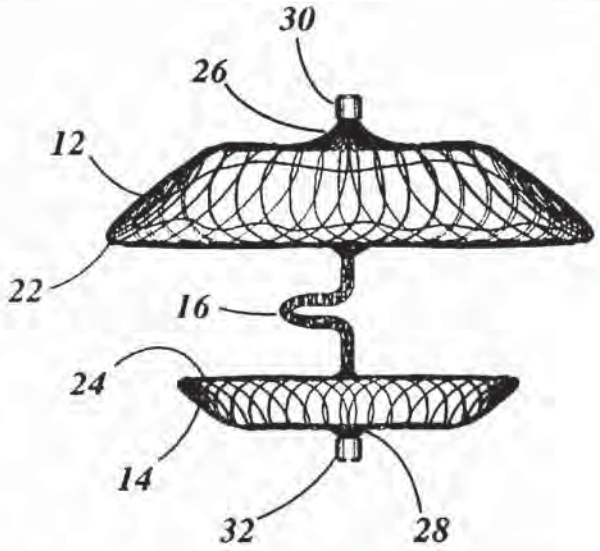
Primary Examiner—Michael Buiz
Assistant Examiner—Vikki Trinh
Attorney, Agent, or Firm—Nikolai, Mersereau & Dietz, P.A.

[57] **ABSTRACT**

A collapsible medical device and associated method for occluding an abnormal opening in, for example, a body organ, wherein the medical device is shaped from a shape memory metal fabric. The device may be used, for example, to non-surgically treat a patient having a Patent Foramen Ovale (PFO) and resulting paradoxical cerebral emboli. The device is preferably made from a continuous tubular metal fabric and includes two outer occluding portions and a resilient central, spring-like interconnecting member. The metal fabric may be heat treated within a mold in order to substantially set a desired shape of the device. The medical device includes a fastener for attaching to the end of a guide wire or delivery catheter. The medical device having the desired relaxed shape may be collapsed and delivered through a catheter or the like for deployment in a desired channel or opening in a patient's body.

30 Claims, 4 Drawing Sheets



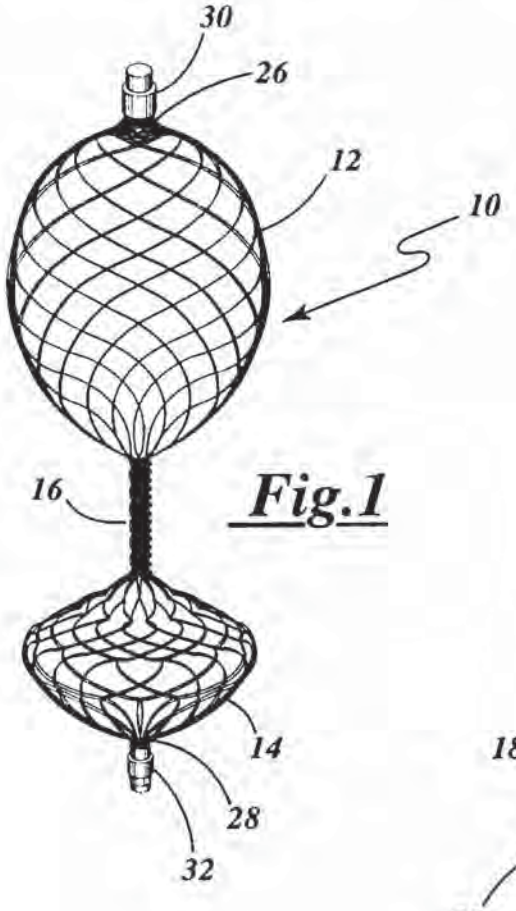


Fig.1

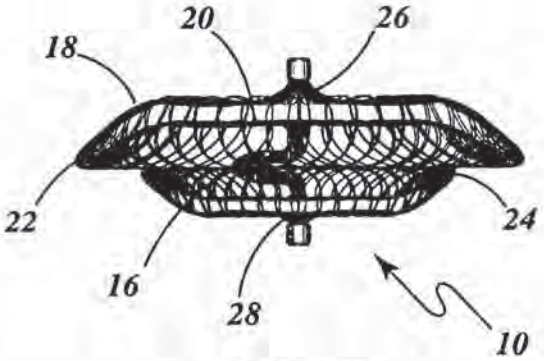


Fig.2

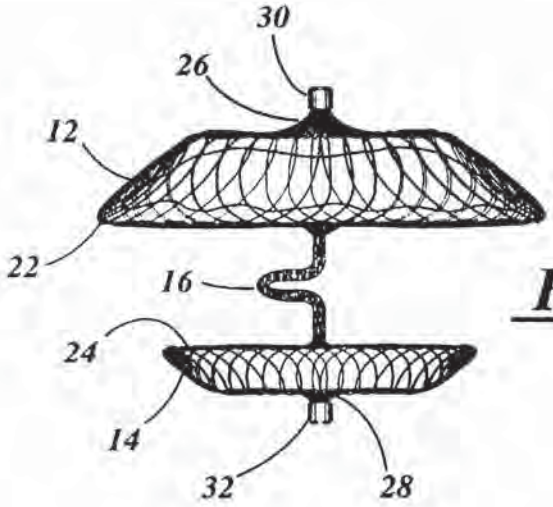


Fig.3

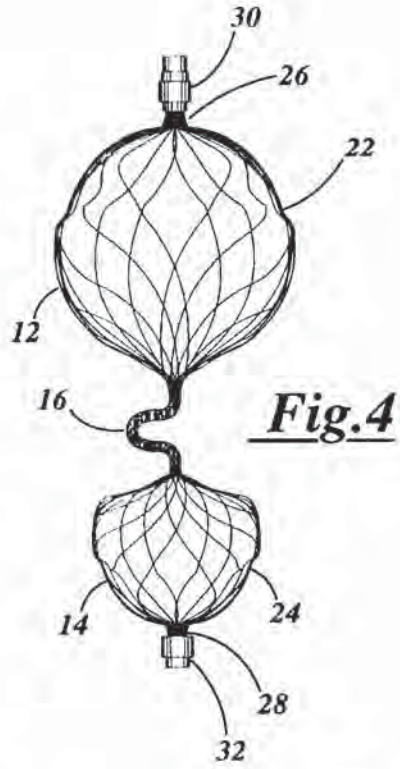


Fig.4

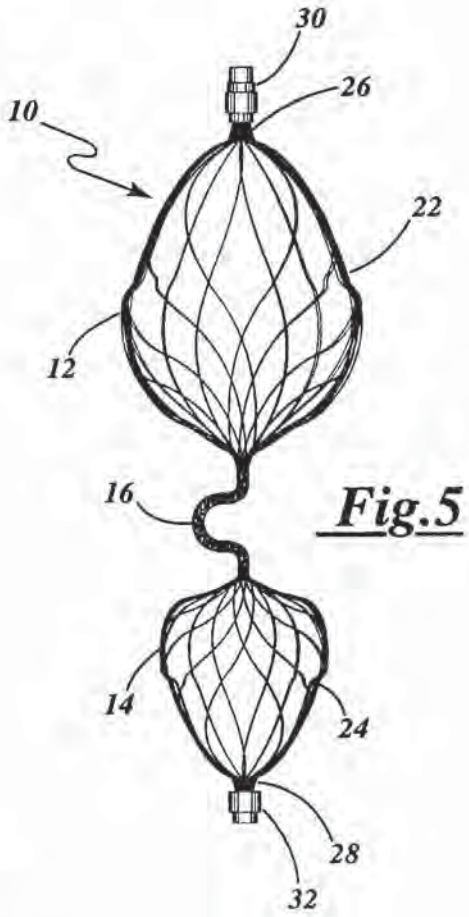


Fig.5

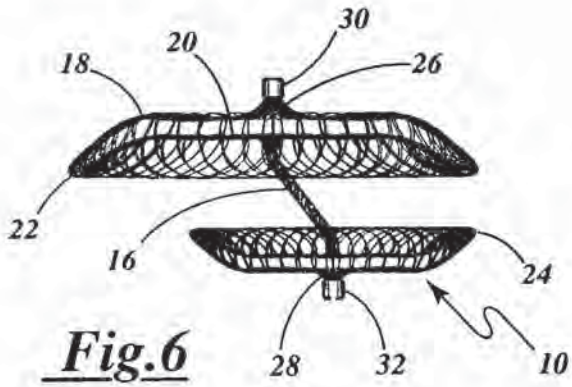


Fig.6

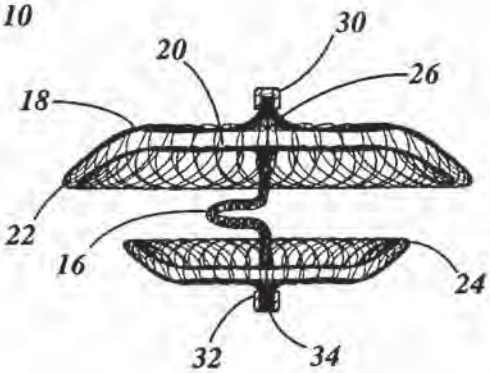


Fig.7

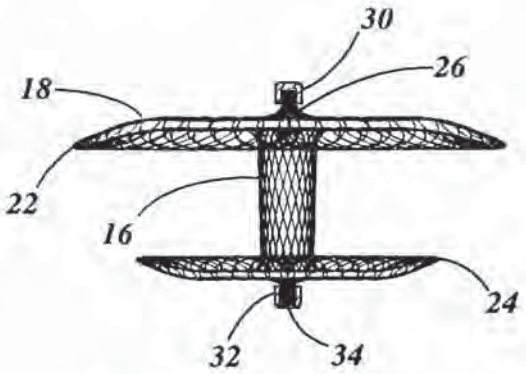


Fig.8

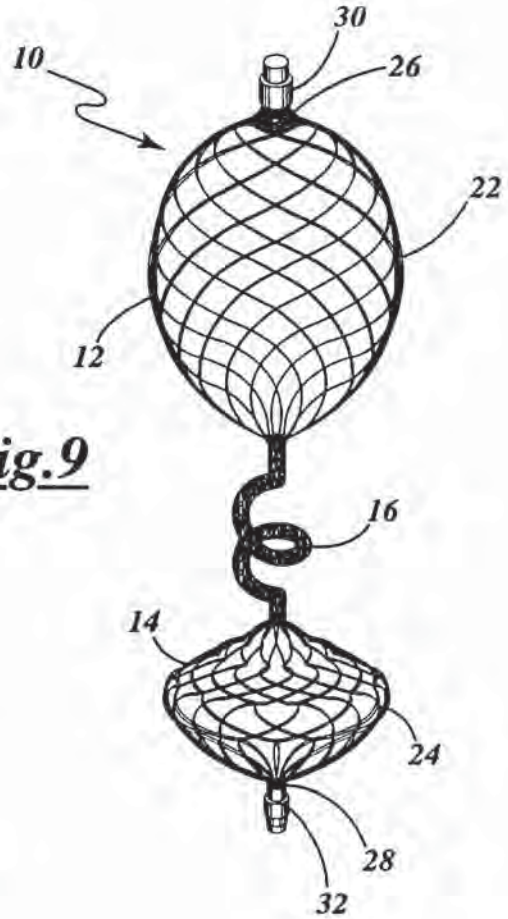


Fig.9

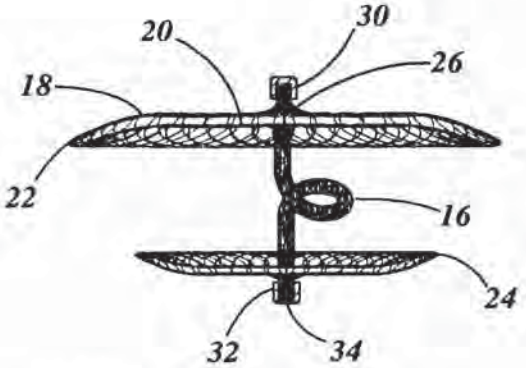


Fig.10

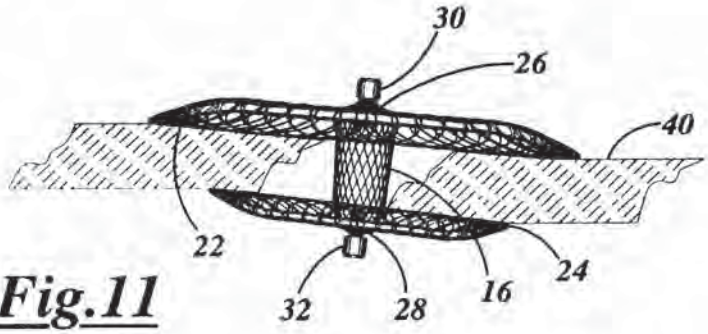


Fig.11

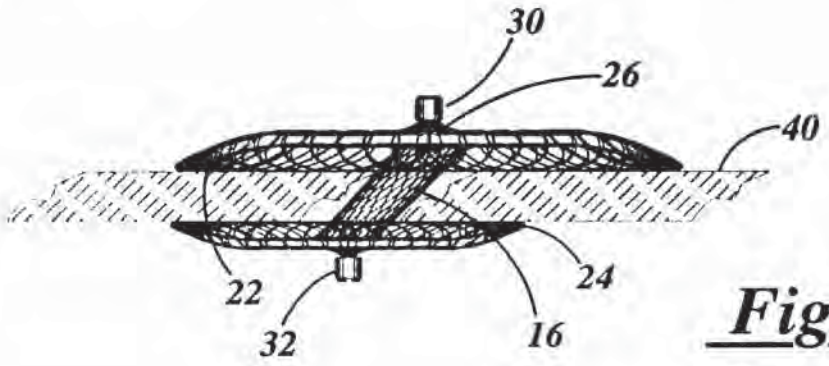


Fig.12

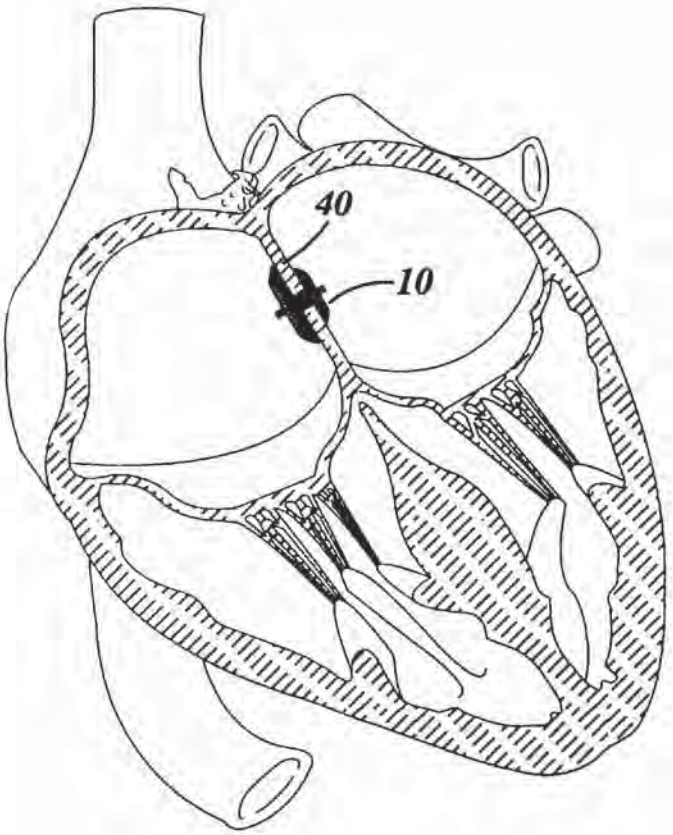


Fig.13

PERCUTANEOUS CATHETER DIRECTED CONSTRICTING OCCLUSION DEVICE

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to a device and non-surgical method for treating certain cardiac defects. More particularly, the present invention relates to a low profile occlusion device for non-surgical treatment of a patient having a Patent Foramen Ovale (PFO) and resulting paradoxical cerebral emboli. The device made in accordance with the invention is capable of automatically adjusting to a septal defect having eccentric openings and is particularly well suited for delivery through a catheter or the like to a remote location in a patient's heart or in analogous vessel or organ within a patient's body.

II. Description of the Related Art

A wide variety of intra cardiac devices are used in various medical procedures. Certain intravascular devices, such as catheters and guide wires, may be used to deliver fluids or other medical devices to a specific location within a patient's heart. For example, a catheter may be used to reach a selective coronary artery within the vascular system or the catheter and/or guidewire may be used to deliver a device to an interior chamber of the patient's heart. Complex devices may be delivered and used in treating specific abnormal conditions, such as devices used in removing vascular occlusions or devices used in treating septal defects and the like.

Balloon catheters and collapsible preformed polymeric devices similar to that disclosed by Landymore et al. in U.S. Pat. No. 4,836,204 and Linden et al. in U.S. Pat. No. 5,634,936 respectively have been used to occlude a septal defect. When using a balloon catheter similar to that disclosed in the '204 patent, an expandable balloon is carried on a distal end of the catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place. The '936 device is expanded and hardened by a ternary system that modifies the pH and hydrophilicity of the device (see '936 patent, col. 6, ln 40–45). If these devices are not expanded completely they may not firmly lodge in the septal defect and may rotate and loosen from the septal wall, thereby releasing into the blood stream. Overfilling the '204 device is an equally undesirable occurrence which may lead to the rupture of the balloon and release of resins into the patient's bloodstream.

Mechanical embolization devices have been proposed in the past for occluding defects in a patient's intravascular system. The devices typically include a pair of spaced apart patches each having an internal collapsible frame (similar to the frame and outer membrane of an umbrella), wherein the opposing patch and frame are interconnected by a conjoint member. The patches are typically aligned and attached to a common axis of the conjoint member. The conjoint member may be a rigid or semi-rigid hub which minimizes the movement of the patches both laterally and fore and aft to thereby firmly retain the patches against the septal wall adjacent the defect. Patches that are attached to a common axis of the hub may become problematic when the septal defect to be occluded has eccentric openings. Since the patches are attached to a common rigid axis, at least one of the eccentric openings may not be completely covered by the respective patch. The rigid or semi-rigid hub prevents adjustment of the patches to compensate for the eccentric openings.

Representative examples of such mechanical devices are disclosed in King et al., U.S. Pat. No. 3,874,388 (the '388 patent), Das, U.S. Pat. No. 5,334,217 (the '217 patent), European application No. 0541,063 A2 (the '063 application), Sideris, U.S. Pat. No. 4,917,089 (the '089 patent), and Marks, U.S. Pat. No. 5,108,420 (the '420 patent). These devices are typically pre-loaded into an introducer or delivery catheter prior to the implantation procedure and are not commonly loaded by the physician during the medical procedure. During deployment of these devices, recapture into the delivery catheter is difficult if not impossible, thereby limiting the effectiveness of these devices.

Prior to implantation of these devices, the thickness of the septal wall near the defect and the approximate width of the defect must be determined in order that an appropriately sized device may be provided. A balloon catheter and a calibrated guidewire having radiopaque regions of known length, may be utilized by a physician during a preliminary fluoroscopic procedure to estimate the defect's size, shape and thickness of the septal wall near the defect. Although useful, the defects exact size and shape cannot be determined, thereby increasing the possibility of leakage around the occluding device. Hence, a device that inherently adjusts to the shape and thickness of the defect would be desirable.

Significantly, the size of the prior devices is inherently limited by the structure and form of the device. Also, when using occluding devices such as those disclosed in the '089, '388, '217, or '420 patents to occlude a septal defect, the pressure and therefore the chance of dislodgment of the device increases with an increase in size of the defect. Consequently, the prior devices require an oversized retention skirt positioned on each side of the defect. Oftentimes, the position of the septal defect dictates the size of the retention skirt. In a membranous type septal defect, it is difficult if not improbable to be able to effectively position the '388, '217, '089, or '420 device without at least partially closing off the aorta. Also, these disclosed devices tend to be rather expensive and time-consuming to manufacture.

Further, the shape of the prior devices (for example squares, triangles, pentagons, hexagons and octagons) require a larger surface contact area and have corners which may extend to the free wall of the atria. Each time the atria contracts (approximately 100,000 times per day) the corners extending to the atria walls are bent, creating structural fatigue fractures in approximately 30 percent of all cases. Furthermore, the previous devices require a French 14–16 introducing catheter, making it impossible to treat children affected with congenital defects with these devices. Hence, it would be advantageous to provide a reliable embolization device which is both easy to deploy through a 6–7 French catheter and which automatically adjusts to the shape and thickness of the defect. The present invention addresses these and other disadvantages of the prior art.

SUMMARY OF THE INVENTION

It is accordingly a principal object of the present invention to provide a reliable, low-profile, intra cardiac occlusion device capable of automatically adjusting the alignment within a septal defect having eccentric openings, wherein the device is suitable for treating septal defects including a

Patent Foramen Ovale (PFO). PFO is essentially a condition wherein an abnormal, wide, opening is present in the septal wall between the two atria of the heart. Blood can flow directly between these two atria, compromising the normal flow of blood and efficiency of the patient's heart. The abnormal opening or septal defect may not extend perpendicularly through the septal wall. Rather, the center of the opening in the septal wall in the left atrium may be eccentric to the center of the opening in the septal wall in the right atrium, thereby requiring eccentric positioned "patches" to effectively occlude the defect. Also, the septal wall may be very thin requiring a minimal separation distance between the two occluding "patches". The device of the present invention is preferably formed from a continuous tubular metal fabric and includes two opposing spaced apart "discs", patches, or retention skirts interconnected by a flexible or resilient central member. The central member flexes both laterally and in the fore and aft directions while providing an inward tension against each of the discs.

When forming these intravascular devices from a resilient metal fabric a plurality of resilient strands or wires are provided, with the metal fabric being formed by braiding the resilient strands to create a resilient material. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the braided fabric in its deformed state. After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in the deformed state. The braided fabric so treated defines a relaxed state of a medical device which can be stretched or expanded and deployed through a catheter into a channel in a patient's body. Those skilled in the art will appreciate that the cavities of the molds must mirror the desired shape of the device and further molding elements are described in co-pending application Ser. No. 08/647,712 filed on May 14, 1996, and entitled PERCUTANEOUS CATHETER DIRECTED INTRAVASCULAR OCCLUSION DEVICE which is assigned to the same assignee as the present invention, the entire disclosure of which is incorporated herein by reference.

The device of the present invention has a specific shape which is particularly well suited for occluding a PFO. The device has a relaxed low-profile configuration and includes clamps that allow attachment of the device to an end of a delivery device or guide wire (allowing recovery of the device after placement). In use, a guide catheter is positioned and advanced in a patient's body such that the distal end of the catheter is adjacent a desired treatment site for treating a physiological condition. The medical device of the present invention having a predetermined shape is then stretched and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon, due to its shape memory property it will tend to substantially return to its relaxed state adjacent the treatment site. The guide wire or delivery catheter is then released from the clamp and removed.

OBJECTS

It is accordingly a principal object of the present invention to provide a device suitable for occluding a septal defect that is capable of automatically adjusting to eccentric openings of the septal defect while providing an inward tension on the occluding portions of the device.

Another object of the present invention is to provide a device suitable for occluding septal defects having eccentric openings, wherein the device is particularly well suited for delivery through a catheter or the like to a remote location in a patient's heart or in an analogous vessel or organ within a patient's body.

A further object of the present invention is to provide an occluding device having outer occluding portions and a flexible resilient central portion that pulls the outer occluding portions together.

These and other objects, as well as these and other features and advantages of the present invention will become readily apparent to those skilled in the art from a review of the following detailed description of the preferred embodiment in conjunction with the accompanying claims and drawings in which like numerals in the several views refer to corresponding parts.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a Patent Foramen Ovale occluding device in accordance with the present invention;

FIG. **2** is a side elevational view of the medical device of the type shown in FIG. **1**;

FIG. **3** is a partial sectional side elevational view of the medical device of the type shown in FIG. **2**, shown partially stretched along its longitudinal axis;

FIG. **4** is a side elevational view of the medical device of the type shown in FIG. **3**, shown stretched along its longitudinal axis slightly more than in FIG. **3**;

FIG. **5** is a side elevational view of the medical device of the type shown in FIG. **4**, shown stretched along its longitudinal axis slightly more than in FIG. **4**;

FIG. **6** is a side elevational view of the medical device of the type shown in FIG. **1** shown partially stretched, wherein the outer perimeter of the spaced apart discs are offset;

FIG. **7** is a partial sectional side elevational view of the medical device of the type shown in FIG. **1**, shown partially stretched along its longitudinal axis;

FIG. **8** is a side elevational view of another embodiment of the present invention shown partially stretched along its longitudinal axis;

FIG. **9** is a side elevational view of another embodiment of the present invention shown partially stretched along its longitudinal axis;

FIG. **10** is a side elevational view of another embodiment of the present invention shown partially stretched along its longitudinal axis;

FIG. **11** is a partial sectional side elevational view of the embodiment of FIG. **8** shown occluding a PFO of the septal wall;

FIG. **12** is a partial sectional side elevational view of the embodiment of FIG. **8** shown occluding a PFO of the septal wall; and

FIG. **13** is a partial sectional side elevational view of the embodiment of FIG. **1** shown occluding an atrial septal defect.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a percutaneous catheter directed occlusion device for use in occluding an abnormal opening in a patient's body that is particularly well suited for occluding a PFO (see FIGS. **11–13**). The occluding device includes two spaced apart occluding members interconnected by a flexible, resilient center portion. A clamp is attached to an outer end of each occluding member, wherein

the clamps are adapted for coupling to the end of a guidewire or catheter for delivery to a pre-selected site within the patient. In the preferred embodiment, the occluding device is formed from a single continuous tubular metal fabric.

The tubular fabric is formed from a plurality of wire strands having a predetermined relative orientation between the strands. Those skilled in the art will appreciate that the pick and pitch of the braided wires may be varied depending upon the desired density of the fabric. The tubular fabric has metal strands which define two sets of essentially parallel generally spiraling and overlapping strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This tubular fabric is known in the fabric industry as a tubular braid.

The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) as well as some other factors, such as the number of wires employed in a tubular braid, the size or diameter of each wire in the braid, and the diameter of the braid are all important in determining a number of important properties of the device. For example, the greater the pick and pitch of the fabric, and hence the greater the density of the wire strands in the fabric, the stiffer the device will be. Also, the greater the diameter of each wire of the braid, the stiffer the device will be. Having a greater wire density will also provide the device with a greater wire surface area, which will generally enhance the tendency of the device to occlude the area in which it is deployed. This thrombogenicity can be either enhanced by a coating of a thrombolytic agent, or abated by a coating of a lubricious, anti-thrombogenic compound. When using a tubular braid to form a device of the present invention, a tubular braid of about 4 mm in diameter having approximately 72 braided wires is suitable for fabricating devices capable of occluding abnormal openings and/or septal defects.

The wire strands of the tubular metal fabric are preferably manufactured from so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

Without any limitation intended, suitable wire strand materials may be selected from a group consisting of a cobalt-based low thermal expansion alloy referred to in the field as ELGELOY, nickel-based high temperature high-strength "superalloys" (including nitinol) commercially available from, for example, Haynes International under the trade name HASTELLOY, nickel-based heat treatable alloys sold under the name INCOLOY by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wire strands is that the wires retain a suitable amount of the deformation induced by a molding surface (as described below) when subjected to a predetermined heat treatment.

In the preferred embodiment, the wire strands are made from a shape memory alloy, NiTi (known as nitinol) which is an approximately stoichiometric alloy of nickel and titanium and may also include other minor amounts of other metals to achieve desired properties. Handling requirements and variations of NiTi alloy composition are known in the art, and therefore such alloys need not be discussed in detail here. U.S. Pat. No. 5,067,489 (Lind) and 4,991,602 (Amplatz et al.), the teachings of which are incorporated herein by reference, discuss the use of shape memory NiTi alloys in guide wires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic and are said to be "super elastic" or "pseudo elastic". This elasticity allows a device of the invention to return to a preset configuration after deployment.

When forming a medical device in accordance with the present invention, an appropriately sized piece of tubular metal fabric is inserted into a mold, whereby the fabric deforms to generally conform to the shape of the cavities within the mold. The shape of the cavities are such that the metal fabric deforms into substantially the shape of the desired medical device. Cores within the cavities may be used to further form the shape of the fabric within the cavities. The ends of the wire strands of the tubular metal fabric should be secured to prevent the metal fabric from unraveling. A clamp or welding, as further described below, may be used to secure the ends of the wire strands.

During the molding procedure, a molding element may be positioned within the lumen of the tubular braid prior to insertion into the mold to thereby further define the molding surface. If the ends of the tubular metal fabric have already been fixed by a clamp or welding, the molding element may be inserted into the lumen by manually moving the wire strands of the fabric apart and inserting the molding element into the lumen of the tubular fabric. By using such a molding element, the dimensions and shape of the finished medical device can be fairly accurately controlled and ensures that the fabric conforms to the mold cavity.

The molding element may be formed of a material selected to allow the molding element to be destroyed or removed from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material. Once the material has been heat treated in contact with the mold cavities and molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The glass shards can then be removed from the enclosure of the metal fabric.

Alternatively, the molding element can be formed of a material that can be chemically dissolved, or otherwise broken down, by a chemical agent which will not substantially adversely affect the properties of the metal wire strands. For example, the molding element can be formed of a temperature resistant plastic resin which is capable of being dissolved with a suitable organic solvent. In this instance, the metal fabric and the molding element can be subjected to a heat treatment to substantially set the shape of the fabric in conformance with the mold cavity and molding element, whereupon the molding element and the metal fabric can be emersed in the solvent. Once the molding element is substantially dissolved, the metal fabric can be removed from the solvent.

Care should be taken to ensure that the materials selected to form the molding element are capable of withstanding the heat treatment without losing its shape, at least until the shape of the fabric has been set. For example, the molding element could be formed of a material having a melting point above the temperature necessary to set the shape of the wire strands, but below the melting point of the metal

forming the strands. The molding element and metal fabric could then be heat treated to set the shape of the metal fabric, whereupon the temperature would be increased to substantially completely melt the molding element, thereby removing the molding element from within the metal fabric.

Those skilled in the art will appreciate that the specific shape of the molding element produces a specific shape of the molded device. If a more complex shape is desired, the molding element and mold may have additional parts including a camming arrangement, but if a simpler shape is being formed, the mold may have few parts. The number of parts in a given mold and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device to which the metal fabric will generally conform.

When the tubular braid, for example, is in its preformed relaxed configuration, the wire strands forming the tubular braid will have a first predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis conforming to the shape of the mold. When the fabric is so deformed the relative orientation of the wire strands of the metal fabric will change. When the mold is assembled, the metal fabric will generally conform to the molding surface of the interior cavity. After undergoing the shape memory process, the resulting medical device has a preset relaxed configuration and a collapsed or stretched configuration which allows the device to be passed through a catheter or other similar delivery device. The relaxed configuration is generally defined by the shape of the fabric when it is deformed to generally to conform to the molding surface of the mold.

Once the tubular or planar metal fabric is properly positioned within a preselected mold with the metal fabric generally conforming to the molding surface of the cavities therein, the fabric can be subjected to a heat treatment while it remains in contact with the molding surface. Suitable heat treatment processing of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils, for example, are used in a number of medical devices, such as in forming the coils commonly carried around distal links of guide wires. A wide body of knowledge exists for forming nitinol in such devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention. Briefly, though, it has been found that holding a nitinol fabric at about 500 degrees centigrade to about 550 degrees centigrade for a period of about 1 to 30 minutes, depending upon the softness or hardness of the device to be made will tend to set the fabric in its deformed state, i.e., wherein it conforms to the molding surface of the mold cavities. At lower temperatures, the heat treatment time will tend to be greater (e.g., about 1 hour at about 350 degrees centigrade) and at higher temperatures the time will tend to be shorter (e.g., about 30 seconds at about 900 degrees centigrade). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors known to those skilled in this field.

Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. In the present invention, this can be accomplished by, for example, connecting electrodes to each end of the metal fabric. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire mold to the desired heat treating temperature in order to heat the metal fabric to the desired temperature. The materials, molding elements and methods of molding a medical device from a tubular or planar metal fabric is further described in co-pending U.S. patent application Ser. No. 08/647,712, filed May 14, 1996 and assigned to the same assignee as the present invention, the entire disclosure of which is incorporated herein by reference.

Heat treating the metal fabric at temperatures ranging between 500–550 degrees centigrade substantially sets the shapes of the wire strands in a reoriented relative position conforming the shape of the fabric to the molding surface. When the metal fabric is removed from the mold, the fabric maintains the shape of the molding surfaces of the mold cavities to thereby define a medical device having a desired shape. After the heat treatment, the fabric is removed from contact with the molding cavity and will substantially retain its shape in a deformed state. If a molding element is used, this molding element can be removed as described above.

The time required for the heat treating process will depend in large part upon the material of which the wire strands of the metal fabric are formed and mass of the mold, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface. The required time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire strands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a super elastic or pseudo elastic phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal will tend to "set" the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

Once a device having a preselected shape has been formed, the device may be used to treat a physiological condition of a patient. A medical device suitable for treating the condition is selected. Once the appropriate medical device is selected, a catheter or other suitable delivery device may be positioned within a channel in a patient's body to place the distal end of the delivery device adjacent the desired treatment cite, such as immediately adjacent (or even within) the shunt of an abnormal opening in the patient's organ for example.

The delivery device (not shown) can take any suitable shape, but desirably comprises an elongate flexible metal shaft having a threaded distal end. The delivery device can be used to urge the medical device through the lumen of a catheter for deployment in a channel of a patient's body. When the device is deployed out the distal end of the catheter, the device will still be retained by the delivery device. Once the medical device is properly positioned within the shunt of the abnormal opening, the distal end of the catheter may be pressed against the medical device and the metal shaft or guidewire can be rotated about its axis to unscrew the medical device from the threaded distal end of the shaft. The catheter and guidewire are then withdrawn.

By keeping the medical device attached to the delivery means, the operator can retract the device for repositioning relative to the abnormal opening, if it is determined that the device is not properly positioned within the shunt. A

threaded clamp attached to the medical device allows the operator to control the manner in which the medical device is deployed out the distal end of the catheter. When the device exits the catheter, it will tend to resiliently return to a preferred relaxed shape. When the device springs back into this shape, it may tend to act against the distal end of the catheter effectively urging itself forward beyond the end of the catheter. This spring action could conceivably result in improper positioning of the device if the location of the device within a channel is critical, such as where it is being positioned in a shunt between two vessels. Since the threaded clamp can enable the operator to maintain a hold on the device during deployment, the spring action of the device can be controlled by the operator to ensure proper positioning during deployment.

The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the distal end of the catheter. For example, the PFO occluding device may have a relatively elongated collapsed configuration wherein the device is stretched along its longitudinal axis (see FIG. **5**). This collapsed configuration can be achieved simply by stretching the device generally along its axis, e.g. by manually grasping the clamps and pulling them apart, which will tend to collapse the relaxed diameter portions of the device inwardly toward the device's axis. Loading such a device into a catheter may be done at the time of implantation and does not require pre-loading of the introducer or catheter.

If the device is to be used to permanently occlude a channel in the patient's body, one can simply retract the catheter and remove it from the patient's body. This leaves the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

When the device is deployed in a patient, thrombi will tend to collect on the surface of the wires. By having a greater wire density, the total surface area of the wires will be increased, increasing the thrombotic activity of the device and permitting it to relatively rapidly occlude the vessel in which it is deployed. It is believed that forming the occlusion device from a 4 mm diameter tubular braid having a pick of at least about 40 and a pitch of at least about 30° will provide sufficient surface area to substantially completely occlude an abnormal opening in the septal wall. If it is desired to increase the rate at which the device occludes, any of a wide variety of known thrombotic agents can be applied to the device. Those skilled in the art will appreciate that an occluding membrane, fiber, or mesh may be positioned within either or both discs **12** and **14** to further enhance the occluding feature of each disc (see FIG. **3**).

Having described the details of the invention, specific reference to the Figures will next be presented. The several Figures illustrate several embodiments of the invention wherein the central portion is resilient and pulls the outer discs towards each other. Referring first to the FIGS. **1** and **2**, there is shown generally the device **10** suitable for occluding a Patent Foramen Ovale (PFO). In its relaxed, unstretched state (see FIG. **2**), the device **10** generally includes two aligned discs **12** and **14** linked together by a resilient central portion **16**. The plurality of braided wires form an outer **18** and inner **20** surface of each disc. The inner surface **20** of each disc may be concave or cupped (see also FIG. **7**) to ensure that the outer perimeter edge **22** and **24** of each disc **12** and **14** respective contacts the septal wall **40**.

When the device **10** is in a relaxed state, the discs **12** and **14** tend to overlap and the central portion **16** extends into the recess formed by the inner surface of the discs **12** and **14**. In this manner, when the discs **12** and **14** are pulled apart (see FIG. **3**) the spring-like action of the central portion **16** will cause the perimeter edge **22** and **24** of the corresponding disc to fully engage the sidewall of the septum (see FIGS. **11** and **12**). FIGS. **3–5** illustrates sequentially the stretching, spring-like action of the bent central portion **16**. Without any limitation intended, during the formation of the device **10**, the tubular braid (in the region forming the central portion **16**) is partially flattened to enhance the spring-like action of the central portion **16**. FIG. **6** illustrates that the discs **12** and **14** may be offset laterally by stretching the central portion **16**.

The ends **26** and **28** of the tubular braided metal fabric device **10** are welded or clamped together with corresponding clamps **30** and **32** to avoid fraying. Of course the ends may alternately be held together by other means readily known to those skilled in the art. Further, it is to be understood that other suitable fastening means may be attached to the ends **26** and **28** in other ways, such as by welding, soldering, brazing, use of biocompatable cementious material or in any other suitable fashion. The clamps **30** and **32** tying together the wire strands at corresponding ends **26** and **28** also serve to connect the device to a delivery system. In the embodiment shown, the clamps **30** and **32** are generally cylindrical in shape and have a threaded bore **34** (see FIG. **7**) for receiving the ends **26** and **28** of the metal fabric to substantially prevent the wires from moving relative to one another. The threaded bore **34** is adapted to receive and engage a threaded distal end of a delivery device.

FIGS. **8–10** show additional embodiments of the device **10** wherein the shape of the resilient central portion **16** is varied. The central portion **16** is flexible in both the lateral and fore and aft directions. This flexibility provides a self centering feature of the device, wherein the discs **12** and **14** tend to automatically center themselves around the adjacent opening of the defect (see FIGS. **11** and **12**) while tending to pull the discs toward the other. The central portion **16** may include a helical spring-like shape (see FIG. **9**), a coil shape (see FIG. **10**), or a bent shape (see FIG. **2**).

Those skilled in the art will appreciate that the device **10** is sized in proportion to the shunt to be occluded. The diameter of each disc **12** and **14** may be varied as desired for differently sized openings in the septal wall. Further, the length of the resilient central portion may be varied depending upon the thickness of the septal wall, and may range between 4 to 40 mm.

The PFO occlusion device **10** can advantageously be made in accordance with the method outlined above. The device is preferably made from a 0.005 inch nitinol wire mesh. The braiding of the wire mesh may be carried out with 28 picks per inch at a shield angle of about 64 degrees using a Maypole braider with 72 wire carriers. The stiffness of the PFO device **10** may be increased or decreased by altering the wire size, the shield angle, the pick size, braid diameter, the number of wire carriers, or the heat treatment process. Those skilled in the art will recognize from the preceding discussion that the cavities of a mold must be shaped consistent with the desired shape of the PFO device.

When using untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of the braid are constrained relative to one another. The clamps **30** and **32** are useful to prevent the braid from unraveling at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps **30** and **32** hold the ends of the cut braid together and prevent the braid from unraveling. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends may be welded together, such as by spot welding with a laser welder. When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual strands will tend to return to their heat set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more economical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device.

Use of a device **10** of the present invention will now be discussed in greater detail with respect to occluding a PFO. The device may be delivered and properly placed using two dimensional echocardiography and Doppler color flow mapping. As indicated above, the delivery device can take any suitable shape, preferably comprising an elongated flexible metal shaft similar to a conventional guide wire. The delivery device is used to advance the PFO occlusion device through the lumen of a small diameter cylindrical tube, such as a delivery catheter, for deployment. The PFO device **10** is loaded into the small diameter cylindrical tube by using a loading sheath to stretch the device and put the same in an elongated or stretched condition. The device may be inserted into the lumen of the tube during the procedure or preassembled at a manufacturing facility, in that the devices of the present invention do not take on a permanent set when maintained in a compressed state.

From a femoral vein approach, the delivery catheter or tube is passed across the PFO. The device **10** is advanced through the delivery catheter until the distal end becomes unconstrained on exiting the end of the catheter, whereupon it assumes its disc-like shape in the left atrium (see FIG. **13**). The delivery catheter is then pulled back in the proximal direction across the PFO and the delivery device is likewise pulled in a proximal direction, urging the distal disc against the septum. The delivery catheter is then further pulled away from the septum, allowing the proximal disc to extend out of the delivery catheter, where it resiliently returns to its predefined relaxed disc-like shape. In this manner, the PFO device is positioned such that the distal disc presses against one side of the septum while the proximal disc presses against the other side of the septum. In order to increase its occluding ability, the device can contain polyester fibers or a nylon fabric (see FIG. **3**). In instances where the device is improperly deployed on a first try, the device may be recovered by pulling the delivery device proximally, thereby retracting the device **10** back into the delivery catheter prior to a second attempt at positioning the device relative to the defect.

When the PFO occluding device is properly placed, the physician rotates the guidewire, unscrewing the threaded distal end of the guidewire from the clamp **30** or **32** of the occluding device **10**. The threads on the clamp are such that the rotation of the guidewire unscrews the guidewire from the clamp of the occluding device **10**, rather than merely rotating the occluding device. As noted above, the threaded clamp can also enable the operator to maintain a hold on the device during deployment, or enables the operator to control the spring action during deployment of the device to ensure proper positioning.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use embodiments of the example as required. However, it is to be understood that the invention can be carried out by specifically different devices and that various modifications can be accomplished without departing from the scope of the invention itself

What is claimed is:

1. A collapsible medical device, comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end, each end having means for securing the metal fabric attached thereto, thereby inhibiting unraveling of the metal fabric, said metal fabric having a relaxed configuration having two enlarged diameter portions and a central portion disposed between the two enlarged diameter portions wherein said central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device further having a collapsed configuration for delivery through a channel in a patient's body.

2. The device as recited in claim **1**, wherein each enlarged diameter portion has an inner and outer wall such that the inner wall of at least one of the enlarged diameter portions is at least partially concave.

3. The device as recited in claim **1**, wherein said central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

4. The device as recited in claim **1**, wherein said central portion is helically shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

5. The device as recited in claim **1**, wherein said central portion is coiled to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

6. The device as recited in claim **1**, wherein said central portion is bent to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

7. The device as recited in claim **2**, wherein said central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

8. The device as recited in claim **1**, wherein a separation distance between the two enlarged diameter portions is less than a thickness of a patient's atrial septum.

9. The medical device as recited in claim **1**, wherein an inner surface of a first enlarged diameter portion is at least partially concave and a length of the central portion is dimensioned such that a perimeter edge of the first enlarged diameter portion overlaps a perimeter edge of a second enlarged diameter portion.

10. The medical device as recited in claim **1**, said two enlarged diameter portions consisting of a first enlarged partially concave diameter portion and a second enlarged partially concave diameter portion.

11. The medical device as recited in claim **1**, said two enlarged diameter portions consisting of a first enlarged diameter portion and a second enlarged diameter portion, wherein the central portion may be flexed such that a first central axis of the first enlarged diameter portion is offset from a second central axis of the second enlarged diameter portion.

12. The medical device as recited in claim 1, wherein said means for securing includes means for attachment to a delivery device.

13. A collapsible medical device, comprising a metal fabric including a plurality of woven metal strands having a proximal end and a distal end, each end having means for securing the metal fabric attached thereto, thereby inhibiting unraveling of the metal fabric, said metal fabric having a relaxed configuration having two enlarged diameter portions and a resilient portion disposed between the two enlarged diameter portions wherein said resilient portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device further having a collapsed configuration for delivery through a channel in a patient's body.

14. The device as recited in claim 13, wherein each enlarged diameter portion has an inner and outer wall such that the inner wall of at least one of the enlarged diameter portions is at least partially concave.

15. The device as recited in claim 13, wherein said resilient portion is shaped to thereby pull the two enlarged diameter portions toward the other.

16. The device as recited in claim 13, wherein said resilient portion is helically shaped to thereby pull the two enlarged diameter portions toward the other.

17. The device as recited in claim 13, wherein said resilient portion is coiled to thereby pull the two enlarged diameter portions toward the other.

18. The device as recited in claim 13, wherein said resilient portion is bent to thereby pull the two enlarged diameter portions toward the other.

19. The medical device as recited in claim 13, said two enlarged diameter portions consisting of a first enlarged diameter portion and a second enlarged diameter portion, wherein the resilient portion may be flexed such that a first central axis of the first enlarged diameter portion is offset from a second central axis of the second enlarged diameter portion.

20. A collapsible medical device, comprising two enlarged diameter portions and a flexible central portion interconnecting the two enlarged diameter portions wherein said flexible central portion allows lateral movement of each of said two enlarged diameter portions with respect to the other, said device having a proximal end and a distal end, wherein at least one of the proximal and distal end includes means for securing said device to a delivery system, said device having a collapsed configuration for delivery through a channel in a patient's body.

21. The device as recited in claim 20, wherein said device is formed from a metal fabric consisting of a plurality of woven metal strands.

22. The device as recited in claim 20, wherein each enlarged diameter portion has an inner and outer wall such that the inner wall of at least one of the enlarged diameter portions is at least partially concave.

23. The device as recited in claim 20, wherein said flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

24. The device as recited in claim 21, wherein said flexible central portion is shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other.

25. The device as recited in claim 20, wherein a separation distance between the two enlarged diameter portions is less than a thickness of a patient's atrial septum.

26. The medical device as recited in claim 20, wherein an inner surface of a first enlarged diameter portion is at least partially concave and a length of the flexible central portion is dimensioned such that a perimeter edge of the first enlarged diameter portion overlaps a perimeter edge of a second enlarged diameter portion.

27. The medical device as recited in claim 20, wherein said means for securing includes means for attachment to a delivery device.

28. The medical device as recited in claim 1, wherein the flexible central portion is shaped to form a stretchable portion, and further wherein the flexible central portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in the relaxed configuration.

29. The medical device as recited in claim 13, wherein the resilient portion is shaped to form a stretchable portion, and further wherein the resilient portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in the relaxed configuration.

30. The medical device as recited in claim 20, wherein the flexible central portion is shaped to form a stretchable portion, wherein the flexible central portion stretches to adjust to a thickness of a patient's atrial septum while the two enlarged diameter portions remain in a preset configuration.

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